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Australian Medicines Terminology
AMT v3 Beta Feedback Summary Results

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Approved for external information

National E-Health Transition Authority

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1 Executive Summary

1.1 Introduction

The Australian Medicines Terminology (AMT) v3 Beta feedback activities conducted with stakeholders during the period of February to April 2013 were aimed at gathering information to ascertain the quality and usability of the AMT v3 Beta product.

The relevant activities included:

1. **AMT v3 Beta survey**

   This online survey was intended to gauge the suitability of the AMT v3 Beta product, focusing on the AMT v3 model components, release files, and gaps in features and documentation. Section 4 includes a summary of the survey responses while Appendix A describes the survey responses in detail.

   A total of 23 users responded to the online survey, representing 21 unique organisations.

2. **AMT v3 webinars and workshops**

   These sessions were aimed at providing education on AMT v3 and gathering feedback from external stakeholders including vendors, jurisdictions, as well as government and research organisations.

   A total of 113 stakeholders attended the webinars (57) and workshops (56).

The feedback received during these activities has been summarised and forms the basis of this report and its recommendations.

1.2 Feedback summary and recommendations

The National Clinical Terminology and Information Service (NCTIS) assessed the responses to identify any issues that may prevent the implementation of AMT v3, and in turn determine any adjustments required to the AMT v3 product (i.e. AMT v3 model, release files and collateral) for the AMT v3 Production release.

Due to the amount of feedback received, only feedback deemed as critical or blockers that will prevent stakeholder implementations of AMT v3 have been included in this report.

The feedback received and the accompanying recommendations to address each item is grouped under the following headings and discussed in detail in Section 5.

- Changes in the AMT v3 Beta model, components, and artefacts
- Changes in the AMT v3 Beta documentation
- User notifications
- AMT business as usual processes
- Other NCTIS projects
- NCTIS product and implementation support

- AMT v3 model, components and documentation after the first v3 Production release
- Work in progress or no further action required

Non-critical feedback is not included in this report, but can be made available to a stakeholder if a request is made. This remaining feedback will be assessed as part of the AMT product development lifecycle. A request for this information can be made via help@nehta.gov.au.

1.3 Summary of changes to AMT v3 model, components and artefacts

The Australian e-Health Research Centre, CSIRO Computational Informatics Division, were contracted by NEHTA to provide independent advice and recommendations for the proposed changes to the AMT v3 model. Their report focused on the following:

- Structural modelling of AMT v3 taking into account the published scope, intended uses and specific business use cases, the underlying Description Logic semantics, the guidelines and constraints imposed by SNOMED CT[1] and, also if there was any missing, incomplete, or ambiguous information.
- Specific high-priority items of feedback as documented in a draft version of the *AMT v3 Beta Survey Summary Results* provided by NEHTA.

The changes summarised below identify modifications to the AMT v3 model published with the AMT v3 Beta released in February 2013. All the changes included in this updated model are the result of the input received during the feedback activities and the CSIRO report.

1 Remodel TPP and CTPP classes as they were in the AMT v2 model.

2 Exclude AMT v2 retired content from AMT v3 release files.

3 Release AMT v3 in Distribution Normal Form.

4 Include TPUU-specific dose forms.

5 Include the *Australian Register of Therapeutic Goods ID reference set*.

6 The MPUU BoSS relationship is optional and *Strength reference set* is mandatory.

7 MPUU *Unit of Use Size* is mandatory.

8 Expand the *Unit of Use Quantity reference set* and the *Subpack Quantity reference set*.

9 Release AMT v3 in Full, Snapshot and Delta formats.

10 Concepts are “Defined” where possible.

A detailed description for each of the v3 model changes including a diagram of the updated AMT v3 model (Figure 1) is provided in Section 6.

The upcoming AMT v3 Pre-Production and Production release data will be compliant with this updated model.

[1] IHTSDO®, SNOMED® and SNOMED CT® are registered trademarks of the International Health Terminology Standards Development Organisation.

2 Introduction

2.1 Purpose

This document summarises the responses from stakeholders received during the Australian Medicines Terminology (AMT) v3 Beta feedback activities, with a focus on the AMT v3 Beta survey. These responses will enable the National Clinical Terminology and Information Service (NCTIS) to assess critical or blocker issues that are preventing the implementation of AMT v3, and this in turn will allow the NCTIS to determine any adjustments required to the AMT v3 product (i.e. AMT v3 model, release files and collateral) for the AMT v3 Production release.

2.2 Intended audience

This document is intended for any stakeholders who are interested in implementing AMT v3 and for those who participated in the AMT v3 Beta feedback gathering activities.

2.3 Scope

This document is limited to discussing feedback received during the AMT v3 Beta feedback activities which were conducted during the period of February to April 2013.

This document does not cover feedback that is unrelated to AMT v3 or that was received outside the AMT v3 Beta feedback activities.

2.4 Overview

The AMT v3 Beta feedback activities are aimed at gathering information to ascertain the quality and usability of the AMT v3 Beta product. The relevant activities where feedback will be drawn are primarily from the AMT v3 Beta survey, supplemented with some feedback received during AMT v3 educational webinars and workshops.

Due to the amount of feedback received, only feedback deemed as critical or blockers that will prevent stakeholder implementations of AMT v3 have been included in this report. Each of these feedback items has a recommendation to address it.

Non-critical feedback is not included in this report, but can be made available to a stakeholder if a request is made. This remaining feedback will be assessed as part of the AMT product development lifecycle. A request for this information can be made via help@nehta.gov.au.

3 AMT v3 Beta feedback gathering activities

The following sub-sections describe briefly the various activities undertaken to gather AMT v3 feedback from stakeholders during the period of February to April 2013. The feedback received from these activities form the basis of this report and its recommendations. A summary of the feedback received along with recommendations on addressing the feedback is described in Section 5.

3.1 AMT v3 Beta survey

A survey was undertaken during the period of February to April 2013 (inclusive) (via Survey Monkey[2]) to gather AMT v3 Beta feedback from stakeholders. The survey is intended to gauge the suitability of the AMT v3 Beta product, focusing on the AMT v3 model components, release files, and gaps in features and documentation.

Section 4 includes a summary of the survey responses while Appendix A describes the survey responses in greater detail.

3.2 AMT v3 webinars and workshops

A series of educational webinars and workshops were held in February, March and April 2013. The sessions were aimed at providing education on AMT v3 and gathering feedback.

Multiple sessions were held in Sydney, Melbourne, Brisbane and Canberra. These sessions were attended by external stakeholders including vendors, jurisdictions, as well as government and research organisations.

A total of 113 stakeholders attended the webinars (57) and workshops (56).

[2] http://www.surveymonkey.net/.

4 AMT v3 Beta survey summary

23 users responded to the survey, representing 21 unique organisations. The complete set of responses with associated diagrams is included in Appendix A.

Respondents who cited “blocker” or “critical” issues were contacted by NCTIS representatives for follow-up analysis, to better understand the issues raised. As a result of discussions between the respondents and the NCTIS, these issues were no longer deemed to be blockers to implementation, but were nonetheless rated as high priority items to be addressed as part of AMT v3 product development. These high priority items along with recommendations to address them are described in Section 5.

5 Feedback summary and recommendations

This section includes a summary of the feedback from the various AMT v3 Beta feedback activities and a recommendation by the NCTIS to address each of the feedback items.

Due to the amount of feedback received, only those deemed as critical or blockers that will prevent stakeholder implementations of AMT v3 have been included. The remaining feedback has not been included in this report and will be assessed as part of the AMT product development lifecycle. Access to this remaining feedback can be requested via help@nehta.gov.au.

Moreover, feedback received that is not specific to the AMT v3 Beta product is also excluded for the purposes of this report.

The Australian e-Health Research Centre, CSIRO Computational Informatics Division, were contracted by NEHTA to provide independent advice and recommendations for the proposed changes to the AMT v3 model. Their report focused on the following:

- Structural modelling of AMT v3 taking into account the published scope, intended uses and specific business use cases, the underlying Description Logic semantics, the guidelines and constraints imposed by SNOMED CT and, also if there was any missing, incomplete, or ambiguous information.
- Specific high-priority items of feedback as documented in a draft version of the *AMT v3 Beta Survey Summary Results* provided by NEHTA.

The following sub-sections summarise the feedback received, along with the accompanying recommendations to address each feedback item. The feedback is grouped by the following headings:

- Changes in the AMT v3 Beta model, components, and artefacts
- Changes in the AMT v3 Beta documentation
- User notifications
- AMT business as usual processes
- Other NCTIS projects
- NCTIS product and implementation support
- AMT v3 model, components and documentation after the first v3 Production release
- Work in progress or no further action required

5.1 Changes in the AMT v3 Beta model, components, and artefacts

The recommendations included in this section reflect a change in the AMT v3 Beta model, components or artefacts. All these changes are in scope of the first AMT v3 Production release.

Section 6 includes the new AMT v3 model, as a result of these changes. The upcoming AMT v3 Production release data will be compliant with this updated model.

See Section 6 for a more detailed description of the v3 model changes that resulted from the following feedback items.

Table 1: Changes in the AMT v3 Beta model, components, and artefacts

Feedback item no.	Feedback item	Recommendation
1	Rationale for TPP vs. CTPP usage – The use case and modelling for each class requires more work and definition. Consider excluding TPP from the v3 model and use CTPP and TPUU instead. This issue has a bearing on CTPP component packs.	• Change TPP and CTPP to reflect a parent-child relationship i.e. back to their representation in the AMT v2 model. • Every component pack CTPP will have a parent TPP. • Refer to Section 6.1 for more details of this change.
2	Consider removal of AMT v2 complete history from the AMT v3 Full release – Inclusion of this complete v2 history may add confusion to users, may not be of benefit to users, majority of users are new to AMT v3 therefore will not need this history and increases time/effort for AMT v3 development and testing which is impacting on a timely release of AMT v3 Production.	• Exclude all AMT v2 history (retired content) from the AMT v3 Full release files for the first AMT v3 Production release. • All inactive components will be excluded i.e. only active components are represented in these files. • From the first AMT v3 Production release onwards, the files will include the usual history mechanism per RF2 specifications. • Refer to Section 6.2 for more details of this model change.
3	Lack of Distribution Normal Form (DNF) in AMT is considered a severe roadblock to effective and safe implementation.	• Release AMT v3 files in DNF format in the first AMT v3 Production release. • This results in changes to the Relationship file and concrete domain reference sets. • Refer to Section 6.3 for more details of this model change.

Feedback item no.	Feedback item	Recommendation
4	AMT v3 Viewer – Not currently included in AMT v3 Beta, but is desirable. A terminology browser is useful for users to help visualise the hierarchical/relational structure of AMT, present quick access to relevant terms and a search functionality to browse a terminology with a lot of content.	• Provide end users with access to an AMT v3 browser from the first AMT v3 Production release onwards.
5	Manufactured dose form may need to be reinstated as active in the AMT v3 model because some trade concepts with a specific dose form cannot be authored in a machine-processable manner.	• Where the TPUU manufactured dose form is a specific form and its associated MPUU manufactured dose form is a parent form, create new TPUU form relationships and release as part of AMT v3 data. • Refer to Section 6.4 for more details of this model change.
6	ARTG IDs are required for use to support mapping and product verification process – This is active in v2 data but is retired in v3 Beta data.	• Develop a new non-defining, annotation type reference set containing ARTG IDs which references CTPP concepts and include in the first AMT v3 Production release. • Cardinality of CTPP concepts and ARTG IDs is many-to-many. • Refer to Section 6.5 for more details of this model change.
7	The HAS AUSTRALIAN BoSS relationship should be optional. Where there is no strength currently recorded for an MPUU, any HAS AUSTRALIAN BoSS relationship should not exist.	• Amend the HAS AUSTRALIAN BoSS relationship to be optional. • Products (MPUUs) without a BoSS strength will not have a HAS AUSTRALIAN BoSS relationship. • Example products affected are non-medicated dressings, nutritional supplements, inert substance and diagnostic strips. • Refer to Section 6.6 for more details of this model change.
8	Make *Unit of use size* mandatory for all MPUUs. This makes the comparison of denominator strength (in the *Strength reference set*) with *Unit of use size* easier – to detect exceptions and data anomalies.	• Make Unit of Use Size mandatory for all MPUUs. • All items without a Unit of Use Size will have "1 each" or "1 unit" represented in the *Unit of use size reference set* e.g. items with continuous dose form. • Refer to Section 6.7 for more details of this model change.

Feedback item no.	Feedback item	Recommendation
9	Add *Unit of use quantity reference set* referencing TPP HAS TPUU relationship and *Subpack Quantity reference set* referencing CTPP HAS SUBPACK relationship to the data and AMT v3 model.	• Add *Unit of use quantity reference set* referencing TPP HAS TPUU relationship and Subpack Qty reference set referencing CTPP HAS SUBPACK relationship to the v3 data. • Refer to Section 6.8 for more details of this model change.
10	Release AMT v3 files in RF2 Full & Snapshot formats for the first AMT v3 Production release. Delta format is not applicable for this first release as it will be an empty file.	• Release AMT v3 files in RF2 Full and Snapshot formats for the first v3 Production release. • Given that all of v2 history is excluded from the first AMT v3 Production release data, the Full and Snapshot formats are essentially identical. • Refer to Section 6.9 for more details of this model change.
11	Concept instances (including grouper concepts) should be defined where possible. For example where a TPUU is completely characterised by its parent TP and MPUU concepts, it should be modelled as Defined. Examples of where this is not possible include the various flavours of Strepsils lozenges (as the flavour attribute is not modelled in the AMT).	• Where an AMT v3 concept is fully characterised by its parent concepts and attributes, they should be modelled as Defined. Otherwise, they are marked as Primitive. • Refer to Section 6.10 for more details of this model change.
12	The AMT v3 TIG SQL scripts need to be revised based on DNF format files and other approved v3 model changes.	• Revise the AMT v3 TIG SQL scripts based on DNF format files and other approved v3 model changes.
13	Make available the AMT v2 data used in transforming to AMT v3 Beta.	• No further action required – AMT v2.26 is available on the NCTIS website for download. • When the first AMT v3 Production release is published, include the AMT v2 version that has been used in the transformation to AMT v3.

5.2 Changes in the AMT v3 Beta documentation

The recommendations included in this section reflect a change in the AMT v3 Beta documentation. These changes are in scope of the first AMT v3 Production release.

Table 2: Changes in the AMT v3 Beta documentation

Feedback item no.	Feedback item	Recommendation
14	The AMT v3 model diagram needs to reflect the relevant approved changes as included in Section 6.	• Amend the AMT v3 model diagram to reflect the relevant changes as included in Figure 1.
15	The MPP and CTPP HAS SUBPACK relationship currently has a cardinality of 0..* to 0..*. This should be 0..* to 0..1.	• Amend the AMT v3 model diagram to reflect 0..1 cardinality for this relationship.
16	There are identical looking Preferred Terms in AMT. Examples are the same TPUU, TPP and CTPP Preferred Terms belonging to different, unique concepts.	• Provide additional implementation guidance to users on the existence and usage of these Preferred Terms.
17	Integration of AMT with SNOMED CT-AU is currently not clearly articulated.	• Integration of AMT with SNOMED CT-AU should commence only when the SNOMED CT *Substance hierarchy* redesign work is complete. • Develop implementation guidance for users intending to associate AMT components with SNOMED CT-AU components (via the *Substance* map). This will provide sample use cases and highlight any modelling constraints of *Substance* concepts in SNOMED CT.

5.3 User notifications

The recommendation included in this section relates to publishing a notification to users. This is in scope of the first AMT v3 Production release.

Table 3: User notifications

Feedback item no.	Feedback item	Recommendation
18	AMT v3 Production release needs to be published as early as possible to encourage adoption, notwithstanding minor defects that can be corrected in later releases.	• Publish a notification to users of AMT v2 releases ceasing after April 2014 – this has already been published. • Publish the AMT v3 Production release as soon as practicable. Currently this is planned for Q2 2014.

5.4 AMT business as usual processes

The recommendations included in this section are to address the feedback items by AMT "business as usual" (BAU) processes. These changes are not in scope of the first AMT v3 Production release.

Table 4: AMT business as usual processes

Feedback item no.	Feedback item	Recommendation
19	Replace specific dose forms within AMT descriptions that are non-clinically significant with their parent dose forms e.g. "tablet: uncoated" to "tablet".	• This issue should be addressed as part of AMT BAU processes; not in scope of the first AMT v3 Production release.
20	MPUUs where Unit of Use is a container type may need to be re-modelled as MPPs. Same with associated TPUUs to become TPPs. Example products are parenteral (injectable) items in vials, ampoules or items in sachets.	• Assess the modelling of the relevant concepts as part of AMT BAU processes.
21	AMT v3 product/content coverage is a critical issue that will hamper implementation.	• Follow up with these two users who provided feedback via the AMT v3 Beta survey to understand the potential gaps in product coverage, and address as part of AMT BAU processes.

5.5 Other NCTIS projects

The recommendations included in this section are to address the feedback items by NCTIS projects other than the AMT v3 project. They will be tracked as part of the appropriate projects.

Table 5: Other NCTIS projects

Feedback item no.	Feedback item	Recommendation
22	Descriptions of multi-component and combination products are unwieldy. They cannot be used in eMM systems.	• Address as part of the Clinical Interface Descriptions project.
23	Develop clinically useful names for users – clinically intuitive names for products with more than three active ingredients are needed.	• Address as part of the Clinical Interface Descriptions project.
24	Barrier to implementation – dose-based prescribing is not currently supported.	• Address as part of the Dose Based Prescribing project.

5.6 NCTIS product and implementation support

The recommendations included in this section are to address the feedback items by NCTIS product and implementation support. These changes are not in scope of the first AMT v3 Production release.

Table 6: NCTIS product and implementation support

Feedback item no.	Feedback item	Recommendation
25	Active MP concepts for multi-component products need to be represented in AMT v3 (i.e. MP for packs with multiple MPUUs). These are active in v2 data but have been retired in v3 Beta data.	• Gather requirements from users on their current usage of this information. • Address this after the first AMT v3 Production release. • It is expected that specific implementation guidance will be made available to address this feedback item.
26	A delta file between the last AMT v2 release and first AMT v3 release may need to be published to support users to migrate to AMT v3.	• Requires further discussion with current users with a live AMT v2 implementation. • If this file is required, make this selectively available only to AMT v2 migrators, not released as part of the v3 release bundle. • Optionally, publish guidance that any AMT v2 component currently implemented but not found in AMT v3 is to be considered as retired.
27	Explanation of reference sets is needed.	• Provide the user with specific reference set training and implementation support. • Include further guidance on Reference Sets in the AMT v3 TIG.

5.7 AMT v3 model, components and documentation after the first v3 Production release

The recommendations included in this section relate to assessing the feedback against the AMT v3 model, components or documentation as part of the AMT v3 product development lifecycle (after the first AMT v3 Production release).

Table 7: AMT v3 model, components and documentation after the first v3 Production release

Feedback item no.	Feedback item	Recommendation
28	Pack size (unit of use quantity) for multi-component products for the full pack (component packs and subpacks) is required – This is active in v2 data but is retired in v3 Beta data.	• Assess the inclusion of this information in the AMT v3 model after the first v3 Production release. • It is expected that specific implementation guidance will be made available to address this feedback item.
29	Non-breaking spaces are required in AMT descriptions.	• Assess the inclusion of non-breaking spaces in AMT v3 descriptions after the first AMT v3 Production release. • This will include identifying rules when non-breaking spaces are needed and validate the rules via the AMT Support Group. Publish the rules as part of the *AMT v3 editorial rules*.
30	Add explanation of complex products in the v3 TIG to improve understanding and increase quality of implementations. Examples include multi-ingredients, multi-components, creams, component packs and non-medicated items. These are often differently modelled and usage of terminology elements will differ.	• Add explanation of complex products in the v3 TIG after the first AMT v3 Production release.
31	Consider adding back Pharmaceutical ingredients in the AMT v3 model and data.	• Need more use-case driven discussion (from Australian users) before considering adding this back into AMT v3. • Investigate the use cases of SNOMED CT Pharmacy model active ingredients. • Address this after the first AMT v3 Production release.

5.8 Work in progress or no further action required

The recommendations included in this section relate to feedback items that are either a work in progress or those that require no further action.

Table 8: Work in progress or no further action required

Feedback item no.	Feedback item	Recommendation
32	Descriptions may have been incorrectly retired while moving from AMT v2 to v3. This mainly relates to TP and TPUU Preferred Terms.	• This is not an issue given the AMT v2 history is to be excluded from the first AMT v3 Production Full release files.
33	The AMT v3 *Language reference set* needs to align with the SNOMED CT-AU *Language reference set* where the content is derived from SNOMED CT-AU.	• No changes needed for the AMT v3 *Language reference set* – this is to prevent file bloat if all of SNOMED CT-AU *Language reference set* content is included.
34	CCA requirements – Vendors may need clear conformance requirements to claim conformant implementations.	• Compliance and conformance requirements are being developed by the NEHTA CCA team. The NCTIS to continue assisting the CCA team in reviews and to participate in the CCA working group.

6 Revised AMT v3 model

The AMT v3 Beta model has been revised in response to the stakeholder feedback described in this document (see Figure 1). The upcoming AMT v3 Pre-Production and Production release data will be compliant with this updated model.

The model diagram reflects the Stated Form of AMT. A separate model diagram that reflects the Distribution Normal Form will be made available subsequently.

The diagram has been created using a combination of UML syntax and the *SNOMED CT Diagramming Guidelines*[3]. Refer to Appendix B for an explanation of the specific elements used in this diagram.

The AMT v3 model diagram is available for download as a separate standalone document from http://www.nehta.gov.au/implementation-resources/ehealth-foundations.

[3] This IHTSDO document is not yet publicly available.

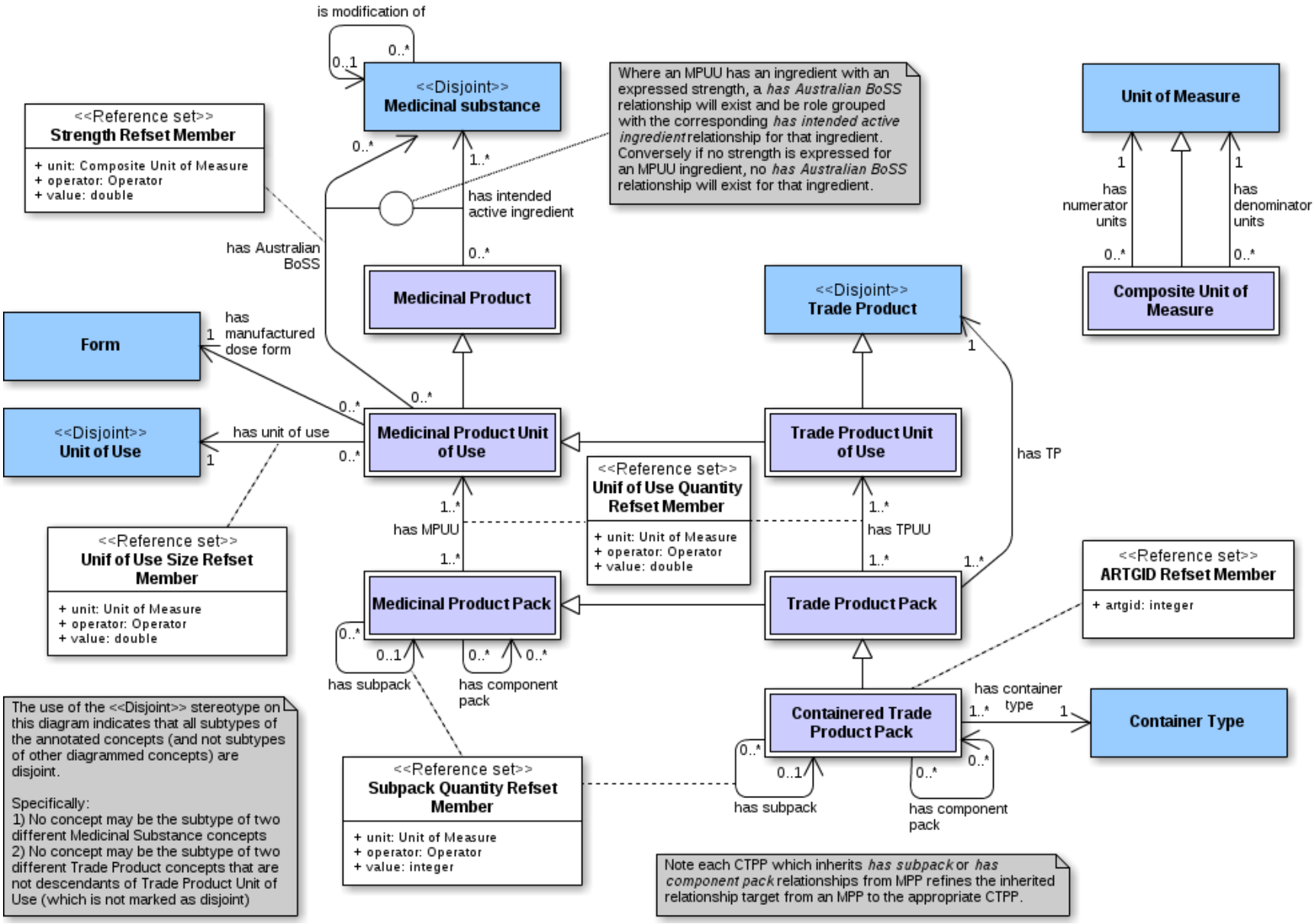


Figure 1: AMT v3 model

The following sub-sections describe the v3 model changes in greater detail.

6.1 Remodel TPP and CTPP classes

In the AMT v2 model, every CTPP is a child concept of a TPP parent concept. Component packs were introduced in the AMT v3 Beta model to allow the modelling of individual containered components of multi-component products (combination kits). CTPP component pack concepts do not have a TPP parent in the v3 Beta model.

Feedback received included users voicing confusion regarding the TPP/CTPP modelling (the previous v2 modelling made more sense) and the development cost of the modelling change to accommodate component packs outweigh its benefit.

Therefore, in the AMT v3 model TPP and CTPP will be remodelled as they were in the AMT v2 model i.e. every CTPP is a child of a TPP parent. Every CTPP component pack will also have a TPP parent.

This remodelling also re-instates the parent-child relationship between TPP and MPP. The CTPP HAS TP and HAS TPUU relationships are no longer modelled, as these attributes are inherited from its TPP parent.

The scope of component packs will also be examined, in particular, parenteral products presenting with an active (injection) component and a diluent will not have component packs created.

6.2 Exclude AMT v2 retired content from AMT v3 release files

The AMT v2 retired content will not be included in v3 content. The AMT v2 content may be retired due to following reasons:

- components not represented or changing definitions in the AMT v3 model
- components that are deemed to be erroneous entries while curating the terminology.

Only active components are represented in the first v3 Production (RF2 Full) files, with each component represented in only one row. The RF2 history mechanism is used to manage component retirement during the AMT v3 lifecycle.

This retired AMT v2 content (i.e. v2 history) is unlikely to be useful for v3 adopters or migrators from v2. It is not clear how v2 content that is carried forward but subject to modelling changes can be meaningfully represented in v3 content. There are currently a small number of v2 adopters who will need to migrate to v3. Direct assistance will be given to users where required to address specific migration issues.

6.3 Release AMT v3 in Distribution Normal Form

AMT v2 and AMT v3 Beta release files are in Stated Form. This indicates that the Relationship file includes only the relationships between concepts that are specifically stated (or modelled) by the terminology authors. This Relationship file does not include any inferred relationships or inherited relationships for concepts.

- An example of an inferred relationship is |*amoxycillin 500 mg + clavulanic acid 125 mg tablet (medicinal product unit of use)*| IS A |*amoxycillin (medicinal product)*|.
- An example of an inherited relationship is |*Zovirax 3% (aciclovir 30 mg / 1 g) eye ointment (trade product unit of use)*| HAS AUSTRALIAN BoSS |*aciclovir (AU substance)*|.

The AMT v3 Relationship file will be released in Distribution Normal Form (DNF), which includes inferred and inherited relationships. This will allow easier access to relationships and concept attributes (where this is required in an implementation) without users manually navigating to different concept levels. This also aligns with the RF2 distribution format of the SNOMED CT international release.

The DNF also includes removing some redundant relationships and retaining only the proximal supertype for IS A relationships between concepts (i.e. IS A relationship to the immediate parent concept).

- An example of a redundant relationship that is removed is |*codeine + paracetamol (medicinal product)*| IS A |*medicinal product*|.
- The following relationships are retained
  - |*codeine + paracetamol (medicinal product)*| IS A |*paracetamol (medicinal product)*|
  - |*codeine + paracetamol (medicinal product)*| IS A |*codeine (medicinal product)*|
  - |*paracetamol (medicinal product)*| IS A |*medicinal product*|
  - |*codeine (medicinal product)*| IS A |*medicinal product*|

Other than the Relationship file the DNF will also have an impact on the AMT v3 concrete domain reference sets (e.g. *Strength reference set*). The inclusion of inferred and inherited relationships will mean additional rows added to the reference sets.

Further details about the DNF can be found in the *AMT v3 Technical Implementation Guide* [1].

6.4 Include TPUU-specific dose forms

In the current AMT v2 data, the manufactured dose form attribute for trade concepts can reflect either a specific form (e.g. tablet: enteric) or a parent form (e.g. tablet). When this attribute is a specific form and the form is deemed clinically significant, the associated medicinal concept also has the specific form.

- For example, both the following concepts will have a form of |*tablet: enteric*|
  - |*Aspirin EC (Pharmacy Choice) (aspirin 100 mg) tablet: enteric (trade product unit of use)*|
  - |*aspirin 100 mg tablet: enteric (medicinal product unit of use)*|

There are currently TPUU concepts with a specific form (that is not clinically significant) while their associated MPUU concepts have a parent form. The specific form for TPUU concepts may be simplified to the parent form, thereby aligning the form with the MPUU concept.

- For example, the following TPUU concept has a specific (but not clinically significant) form of |*tablet: film-coated*| but its associated MPUU concept has a parent form of |*tablet*|. The TPUU form may be simplified to |*tablet*|.
    - The TPUU concept |*Avanza (mirtazapine 45 mg) tablet: film-coated (trade product unit of use)*| is amended to |*Avanza (mirtazapine 45 mg) tablet (trade product unit of use)*|
    - The associated MPUU concept is |*mirtazapine 45 mg tablet (medicinal product unit of use)*|

AMT v3 data will reflect the same data as AMT v2 i.e. where TPUU concepts have a specific form and their MPUU concepts have a parent form this is retained as separate TPUU HAS MANUFACTURED DOSE FORM and MPUU HAS MANUFACTURED DOSE FORM relationships.

6.5 Include ARTG ID reference set

The Australian Register of Therapeutic Goods[4] (ARTG) IDs from AMT v2 were not included in the AMT v3 Beta model. Feedback was received to include them to support mappings and product verification.

ARTG IDs (also known as Licence IDs) will be released in AMT v3 as a non-defining, annotation type reference set. Each row will reference a CTPP concept and includes an associated ARTG ID (as a string).

The cardinality will be many-to-many because some CTPP concepts have multiple ARTG IDs (these are rare occurrences) while some ARTG IDs refer to multiple CTPP concepts. The majority of CTPP concepts have only one associated ARTG ID.

- An example of a CTPP having multiple ARTG IDs is |*Seretide MDI 125/25 inhalation: pressurised, 120 actuations, metered dose aerosol can*|
    - This CTPP has two ARTG IDs of 77830 and 120662 (sample pack).
- An example of multiple CTPPs per ARTG ID is the product Abilify 5 mg tablets, which presents in 11 different pack sizes. All have the same ARTG ID of 90925. Some examples of the different pack sizes are:
    - |*Abilify 5 mg tablet: uncoated, 10, blister pack*|
    - |*Abilify 5 mg tablet: uncoated, 30, blister pack*|
    - |*Abilify 5 mg tablet: uncoated, 60, blister pack*|

[4] http://www.tga.gov.au/industry/artg.htm#.UsT_D1IkHng

6.6 MPUU BoSS relationship is optional and Strength reference set is mandatory

In the AMT v3 Beta model and data, the HAS AUSTRALIAN BoSS relationship is mandatory for all MPUU concepts while the *Strength reference set* is optional. This covered products that had an associated BoSS substance but no reported strength details e.g. non-medicated dressings, nutritional supplements, diagnostic strips and inert substances.

Due to the definition of the BoSS[5], it is more accurate to model products with no reported strength as having no associated BoSS substance. Therefore, in AMT v3 the HAS AUSTRALIAN BoSS relationship is optional and the *Strength reference set* is mandatory.

Products (MPUU concepts) with no reported strength will have no HAS AUSTRALIAN BoSS relationships. These products will not have relationship groups as a consequence of not having HAS AUSTRALIAN BoSS relationships.

6.7 MPUU Unit of Use Size is mandatory

In the AMT v3 Beta data, every MPUU has a *Unit of use*. Examples include “tablet”, “capsule”, “ampoule”, “vial”, “jar” and “continuous”. However Unit of use size is optional.

For many products, an associated *Unit of use size* is included where this can be defined and is manifested as entries in the *Unit of use size reference set*. Examples include 1 tablet, 1 capsule, 1 ampoule, 5 mL and 50 mg. Continuous dose form products (e.g. solutions, creams and ointments) do not have a *Unit of use size* because it is not possible to provide a consistent *Unit of use size* as a precise amount (i.e. the smallest administrable dose unit cannot be defined or is variable). Products that present in multi-dose preparations also do not have a *Unit of use size* e.g. Nilstat oral drops. Therefore, these products do not have an entry in the AMT v3 Beta *Unit of use size reference set*.

Unit of use size will be made mandatory in AMT v3 Production. This is to facilitate more accurate modelling of the products currently without a *Unit of use size* by aligning the *Unit of measure* recorded for both the *Unit of use size reference set* and the *Strength reference set*. The *Unit of use size* is also used in conjunction with the *Strength* value (in the *Strength reference set*) to calculate the non-normalised strength value (the human readable numerator/denominator strength details as displayed in the MPUU Preferred Terms).

For example the MPUU |*amoxycillin 250 mg/5 mL oral liquid: powder for*| has a Unit of use size of “5 mL” and a normalised strength (in the *Strength reference set*) of “50 mg/mL”. Combining these two attributes results in the calculated strength details of “250 mg/5 mL”.

[5] The BoSS is the name of the ingredient that the strength of the product is based on. It may be a base, primary modified base or secondary modified base.

6.8 Expand Unit of Use Quantity and Subpack Quantity reference sets

The HAS TPUU relationship is a sub-role of the HAS MPUU relationship. In AMT v3 Beta the *Unit of use quantity* attribute exists only for the HAS MPUU relationship but not for the HAS TPUU relationship. *Unit of use quantity* is an essential attribute of TPP concepts, therefore it will be added in AMT v3 Production (manifested as additional entries in the *Unit of use quantity reference set*, referencing HAS TPUU relationships).

Similarly, *Subpack quantity* is an essential attribute of certain CTPP concepts but only exists for some MPP concepts in AMT v3 Beta. Therefore, it will be added as additional entries in the *Subpack Quantity reference set*, referencing CTPP HAS SUBPACK relationships in AMT v3 Production.

6.9 Release AMT v3 in Full, Snapshot and Delta formats

AMT v2 and v3 Beta releases are in the RF2 Snapshot format i.e. every component is listed once in the release file, in their latest state. In RF2 specifications a Full release type is mandatory. Therefore, AMT v3 Production will include a Full release type. A Full release contains the full history of every component since its introduction into the terminology. A Snapshot release will continue to be published in AMT v3 Production as this is the most useful release type for implementers.

Since all AMT v2 retired content will be excluded in AMT v3 (see Section 5.2), there is no component history to be included in the release files, and the Full and Snapshot releases will be identical.

A Delta release will not be included in the first AMT v3 Production release as this will merely be a blank file. Later AMT v3 releases will include a delta release.

6.10 Concepts are “Defined” where possible

When a concept is fully characterised by its parent concepts and set of attributes, it is deemed to be “Defined”. If its parent concepts and attributes are not sufficient to fully characterise a concept, it is deemed to be Primitive.

In the AMT v3 Beta data, some concepts like TPUU and TPP concepts, and some grouper concepts (e.g. |*medicinal product*|) are marked as Primitive. Where possible these concepts will be marked as Defined in AMT v3 Production.

To illustrate, most TPUU concepts are sufficiently characterised (i.e. Defined) because they have sufficient attributes (included in the terminology) that represent its definition i.e. the attributes of Trade Product, BoSS, BoSS strength, Form and Unit of Use. These attributes are inherited from its super-type concepts of TP, MP and MPUU.

- An example of a Defined TPUU concept is
  |*Abisart (irbesartan 150 mg) tablet (trade product unit of use)*|

However some TPUU concepts remain as Primitive because they have some unmodelled attribute as part of their definition (not included in the terminology).

- For example, |*Strepsils orange (amylmetacresol 600 microgram + dichlorobenzyl alcohol 1.2 mg) lozenge (trade product unit of use)*| has an unmodelled Flavour attribute value of “orange”.

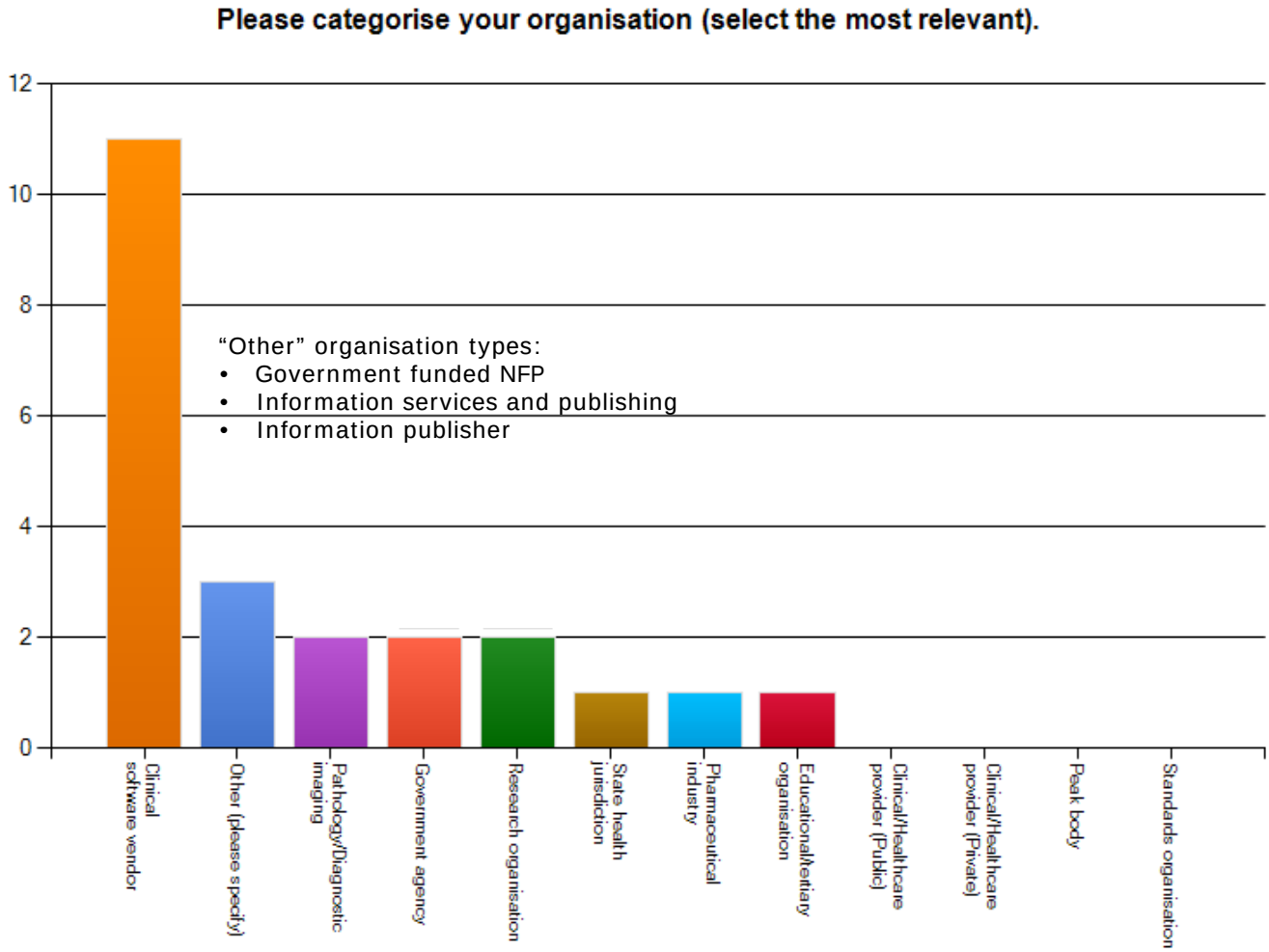
Appendix A AMT v3 Beta survey results

The following sub-sections detail the responses received for each of the 21 survey questions. Most of the responses are described using graphs.

Question 1: Please provide your details.

(Details omitted to maintain anonymity of respondents.)

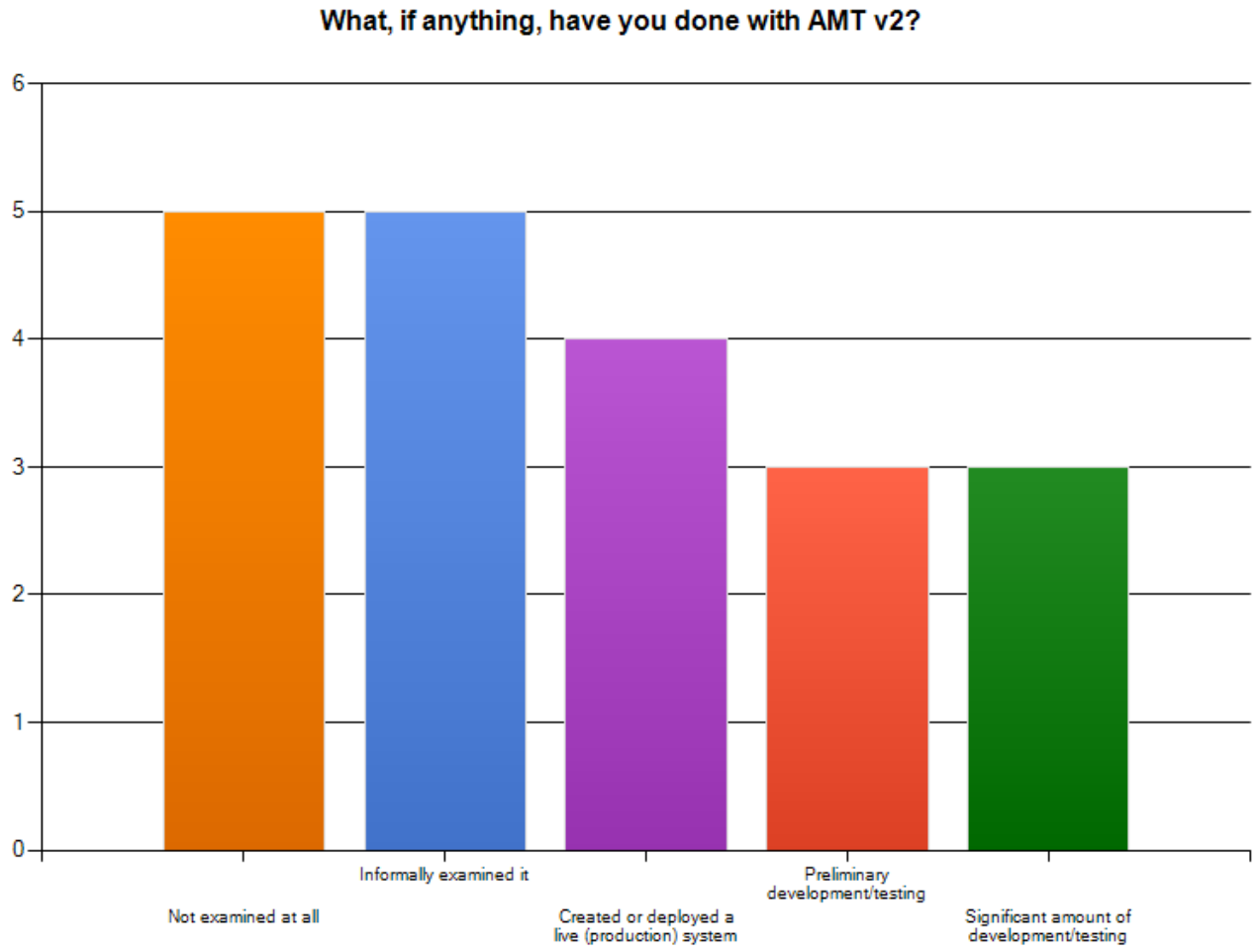
Question 2: Please categorise your organisation (select the most relevant).



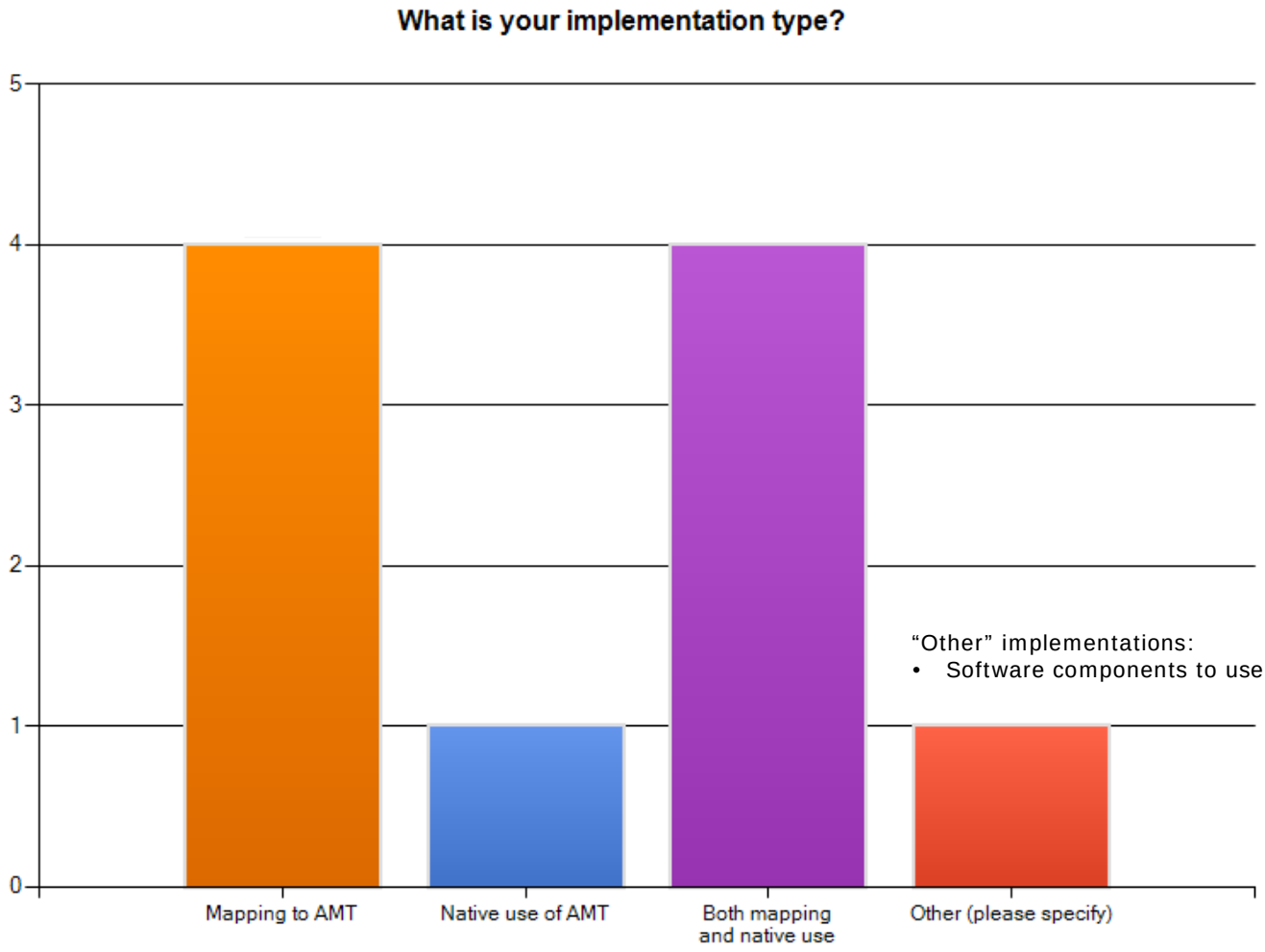
"Other" organisation types:

- Government funded NFP
- Information services and publishing
- Information publisher

Question 3: What, if anything, have you done with AMT v2?



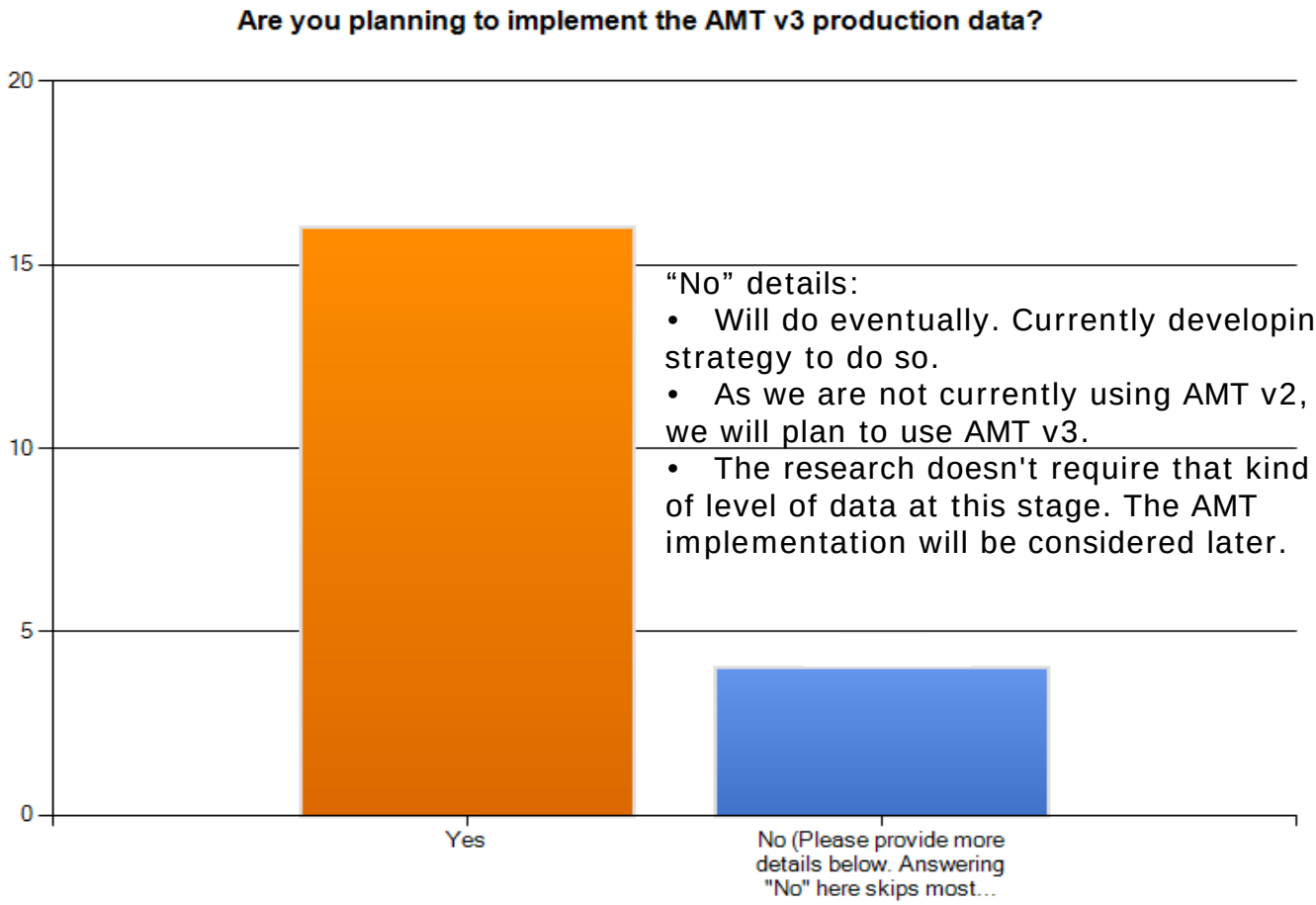
Question 4: What is your implementation type?



"Other" implementations:

- Software components to use AMT

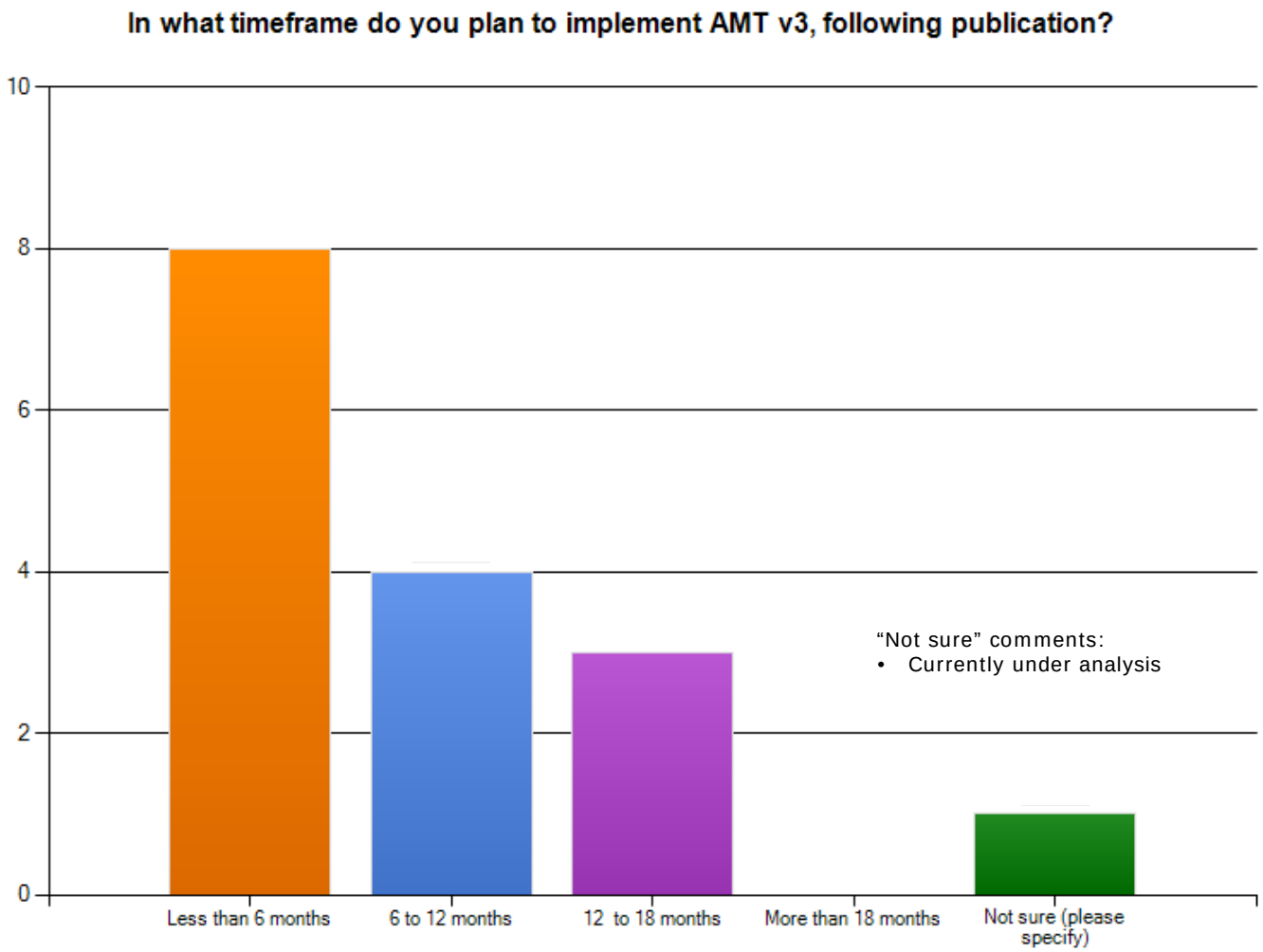
Question 5: Are you planning to implement the AMT v3 production data?



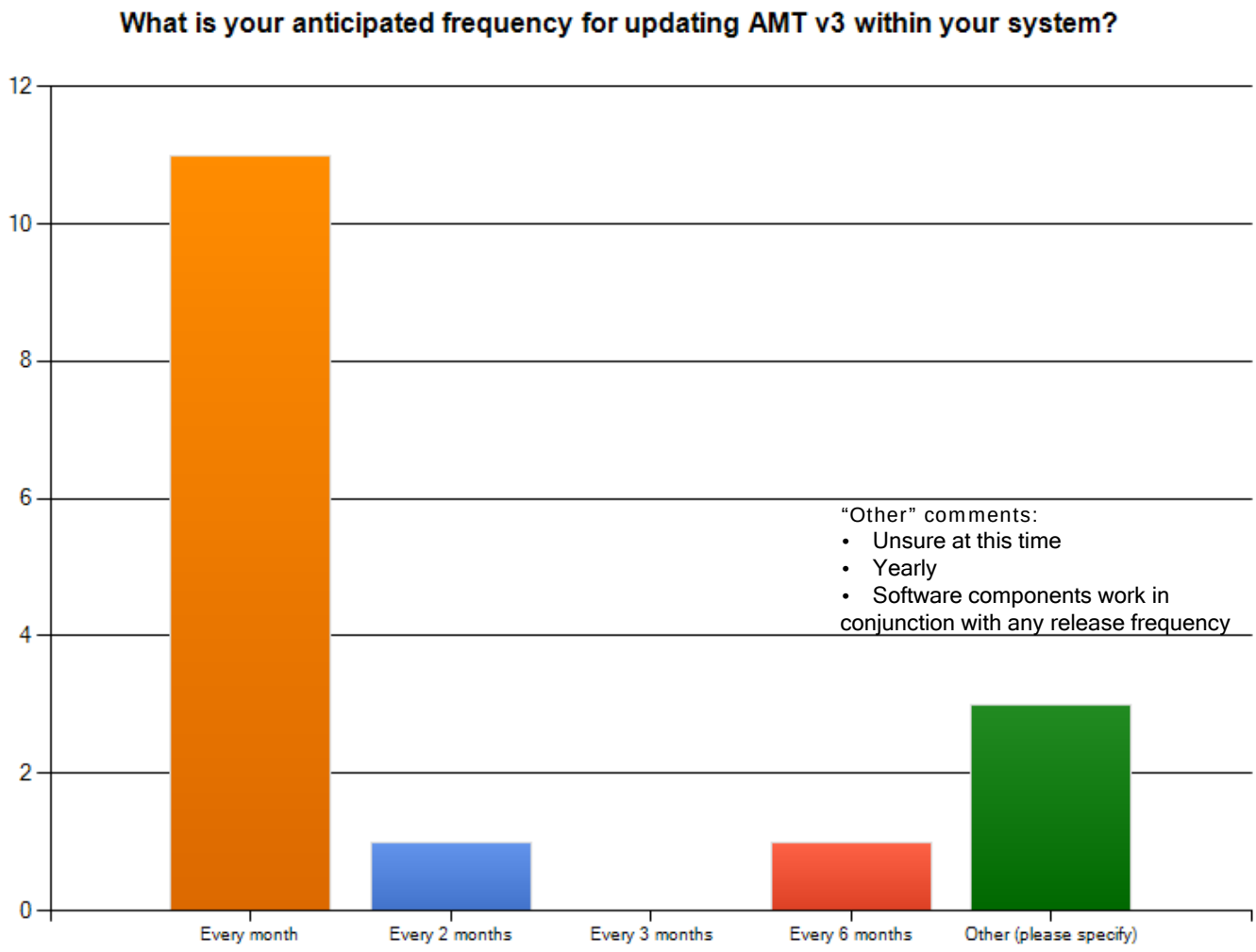
"No" details:

- Will do eventually. Currently developing strategy to do so.
- As we are not currently using AMT v2, we will plan to use AMT v3.
- The research doesn't require that kind of level of data at this stage. The AMT implementation will be considered later.

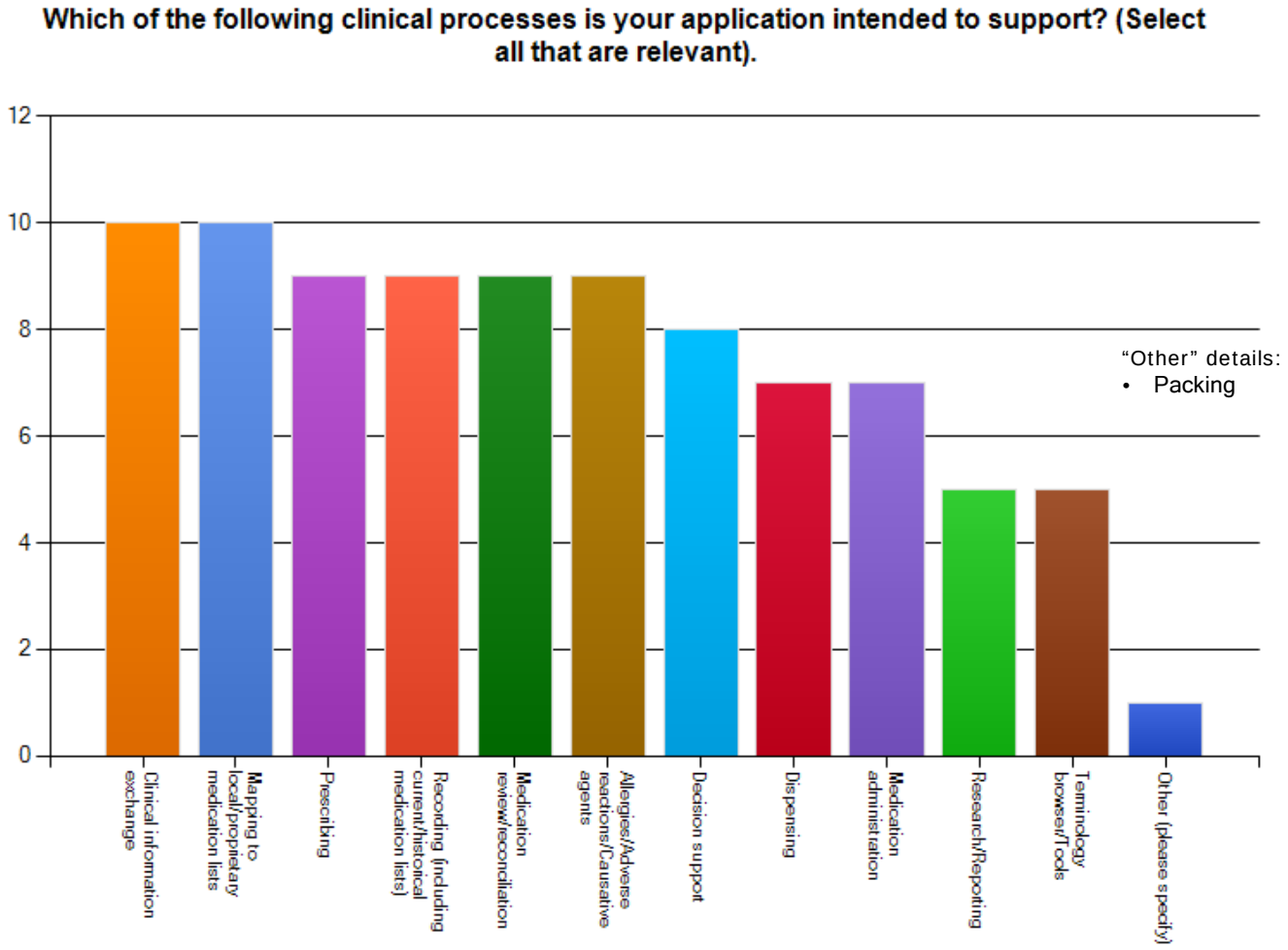
Question 6: In what timeframe do you plan to implement AMT v3, following publication?



Question 7: What is your anticipated frequency for updating AMT v3 within your system?



Question 8: Which of the following clinical processes are your application intended to support? (Select all that are relevant.)

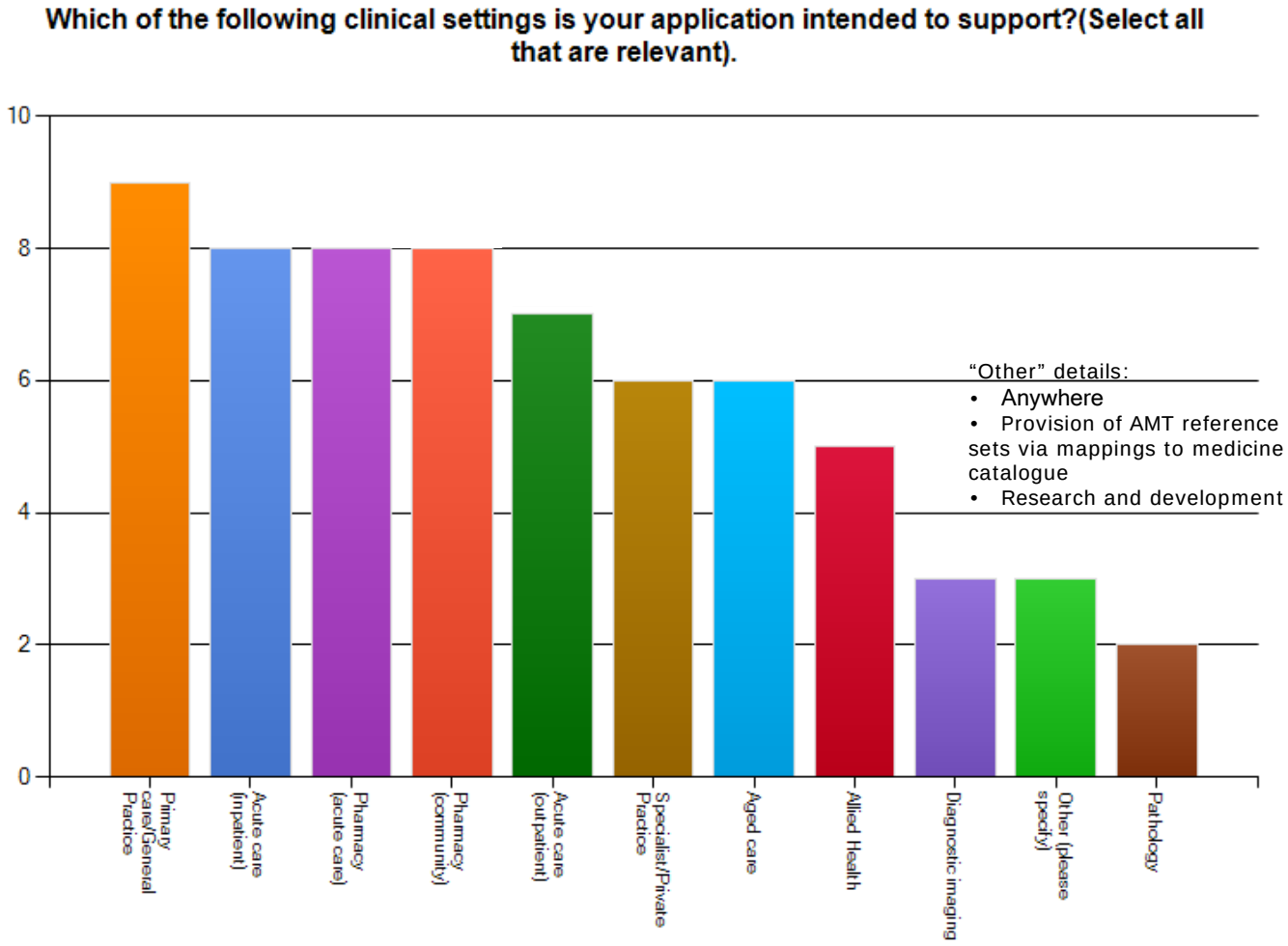


Which of the following clinical processes is your application intended to support? (Select all that are relevant.)

Answer Options	Response Percentage	Response Count
Prescribing	10.1%	9
Dispensing	8.0%	7
Clinical information exchange	11.2%	10
Medication administration	7.9%	7
Recording (including current/historical medication lists)	10.1%	9
Medication review/reconciliation	10.1%	9
Decision support	9.0%	8
Allergies/Adverse reactions/Causative agents	10.1%	9

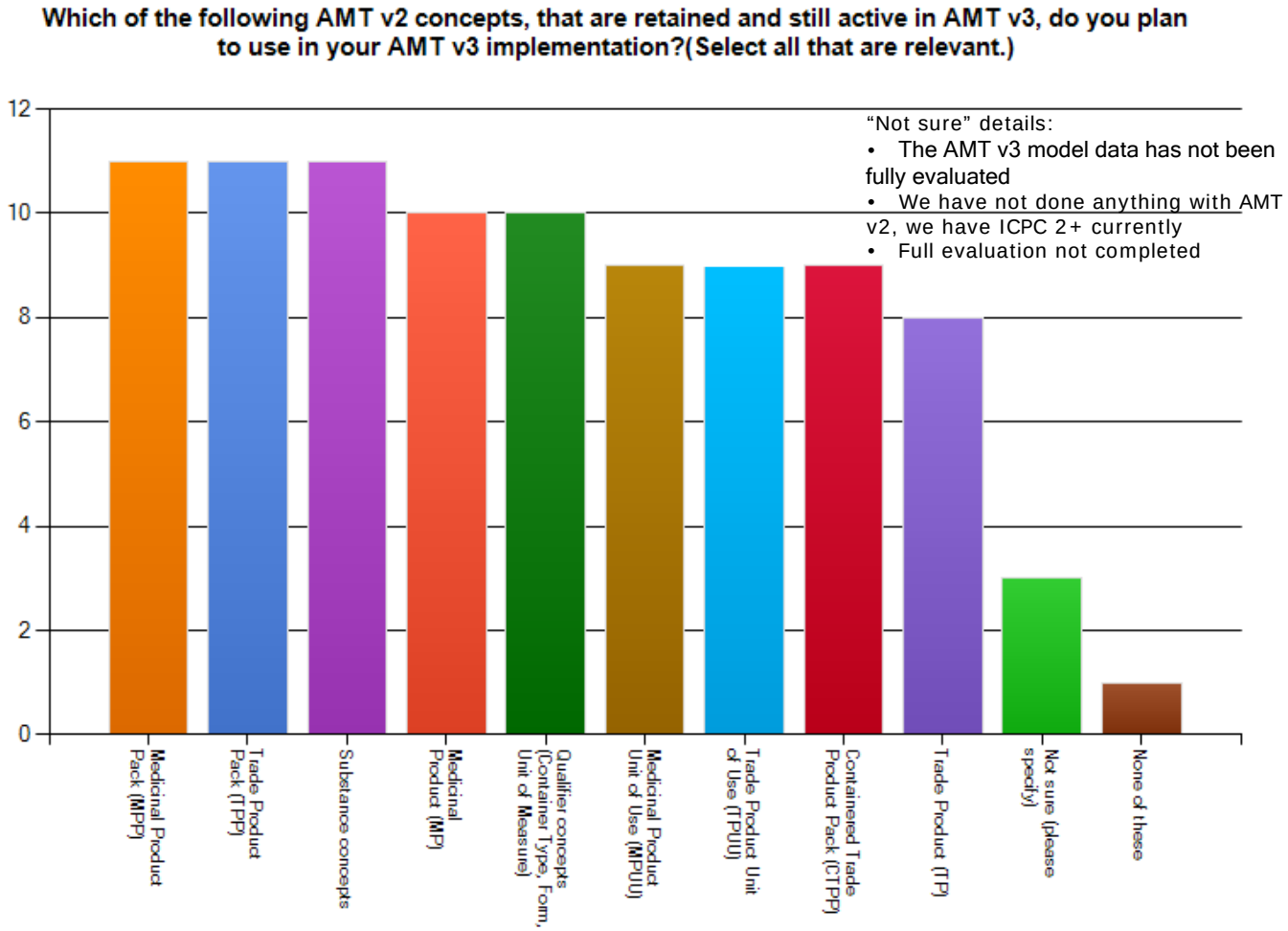
Which of the following clinical processes is your application intended to support? (Select all that are relevant.)		
Answer Options	**Response Percentage**	**Response Count**
Research/Reporting	5.6%	5
Terminology browser/Tools	5.6%	5
Mapping to local/proprietary medication lists	11.2%	10
Other (please specify)	1.1%	1

Question 9: Which of the following clinical settings is your application intended to support? (Select all that are relevant.)



Which of the following clinical settings is your application intended to support? (Select all that are relevant.)		
Answer Options	**Response Percentage**	**Response Count**
Primary care/General Practice	13.8%	9
Acute care (inpatient)	12.3%	8
Acute care (outpatient)	10.8%	7
Specialist/Private Practice	9.2%	6
Pharmacy (acute care)	12.3%	8
Pharmacy (community)	12.3%	8
Allied Health	7.7%	5
Aged care	9.2%	6
Pathology	3.2%	2
Diagnostic imaging	4.6%	3
Other (please specify)	4.6%	3

Question 10: Which of the following AMT v2 concepts, that are retained and still active in AMT v3, do you plan to use in your AMT v3 implementation? (Select all that are relevant.)

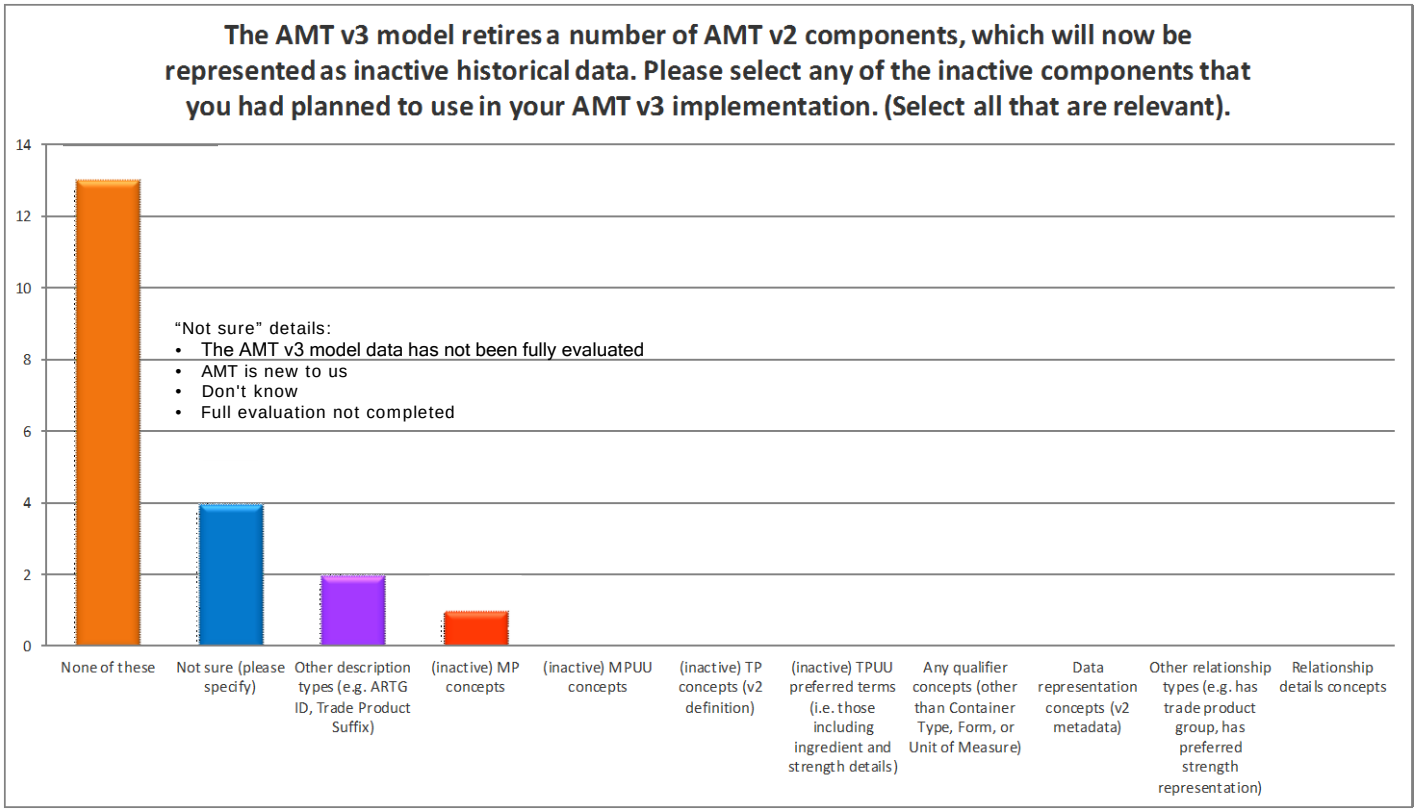


Which of the following AMT v2 concepts, that are retained and still active in AMT v3, do you plan to use in your AMT v3 implementation? (Select all that are relevant.)

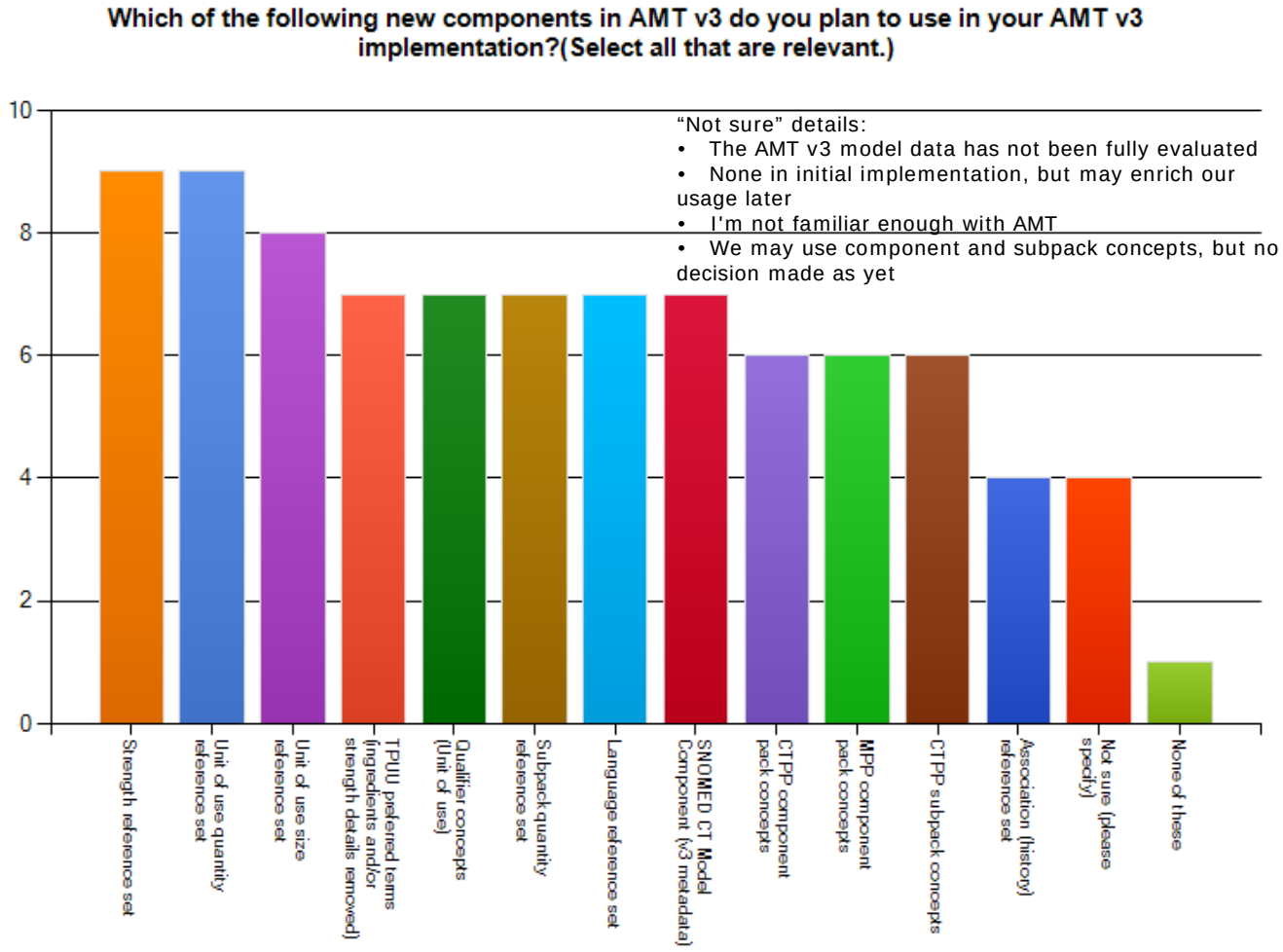
Answer Options	Response Percentage	Response Count
Medicinal Product (MP)	10.9%	10
Medicinal Product Unit of Use (MPUU)	9.8%	9
Medicinal Product Pack (MPP)	11.9%	11
Trade Product (TP)	8.7%	8
Trade Product Unit of Use (TPUU)	9.8%	9
Trade Product Pack (TPP)	11.9%	11
Containered Trade Product Pack (CTPP)	9.8%	9
Substance concepts	11.9%	11

Which of the following AMT v2 concepts, that are retained and still active in AMT v3, do you plan to use in your AMT v3 implementation? (Select all that are relevant.)		
Answer Options	**Response Percentage**	**Response Count**
Qualifier concepts (Container Type, Form, Unit of Measure)	10.9%	10
None of these	1.1%	1
Not sure (please specify)	3.3%	3

Question 11: The AMT v3 model retires a number of AMT v2 components, which will now be represented as inactive historical data. Please select any of the inactive components that you had planned to use in your AMT v3 implementation. (Select all that are relevant.)



Question 12: Which of the following new components in AMT v3 do you plan to use in your AMT v3 implementation? (Select all that are relevant.)

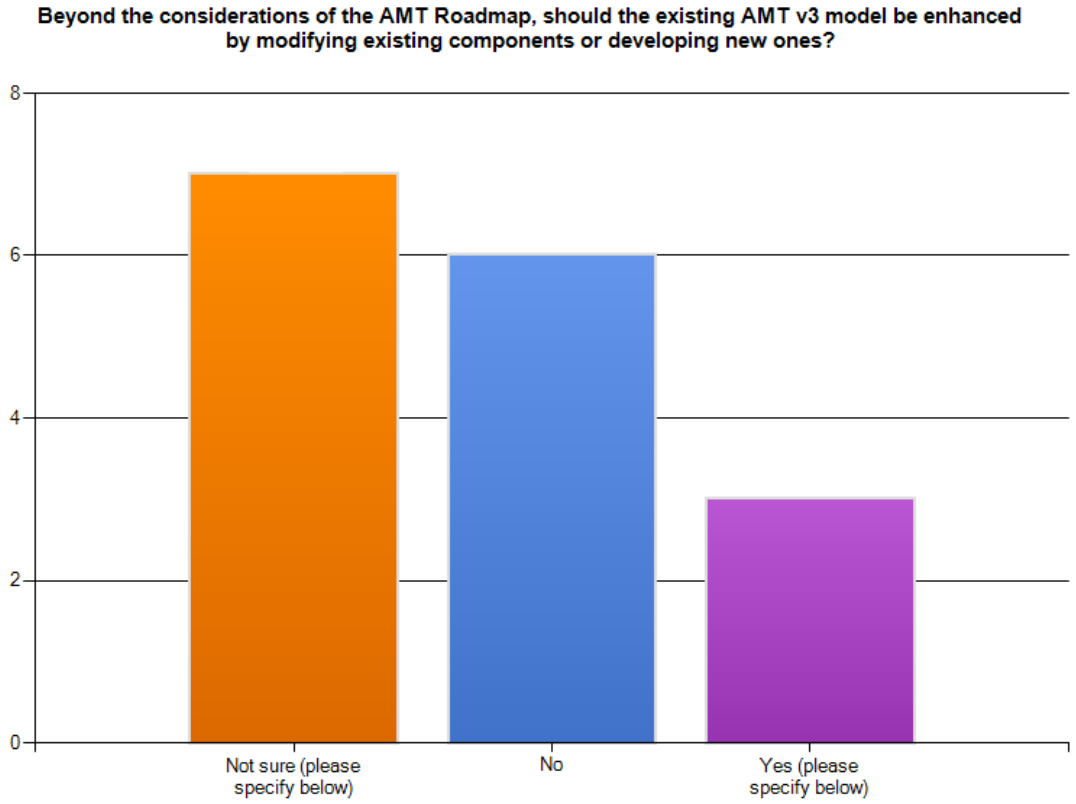


Which of the following new components in AMT v3 do you plan to use in your AMT v3 implementation? (Select all that are relevant.)

Answer Options	Response Percentage	Response Count
CTPP component pack concepts	6.8%	6
MPP component pack concepts	6.8%	6
CTPP subpack concepts	6.8%	6
TPUU preferred terms (ingredients and/or strength details removed)	8.0%	7
Qualifier concepts (Unit of use)	8.0%	7
Strength reference set	10.2%	9
Unit of use quantity reference set	10.2%	9

Which of the following new components in AMT v3 do you plan to use in your AMT v3 implementation? (Select all that are relevant.)		
Answer Options	**Response Percentage**	**Response Count**
Unit of use size reference set	9.1%	8
Subpack quantity reference set	8.0%	7
Language reference set	8.0%	7
Association (history) reference set	4.5%	4
SNOMED CT Model Component (v3 metadata)	8.0%	7
None of these	1.1%	1
Not sure (please specify)	4.5%	4

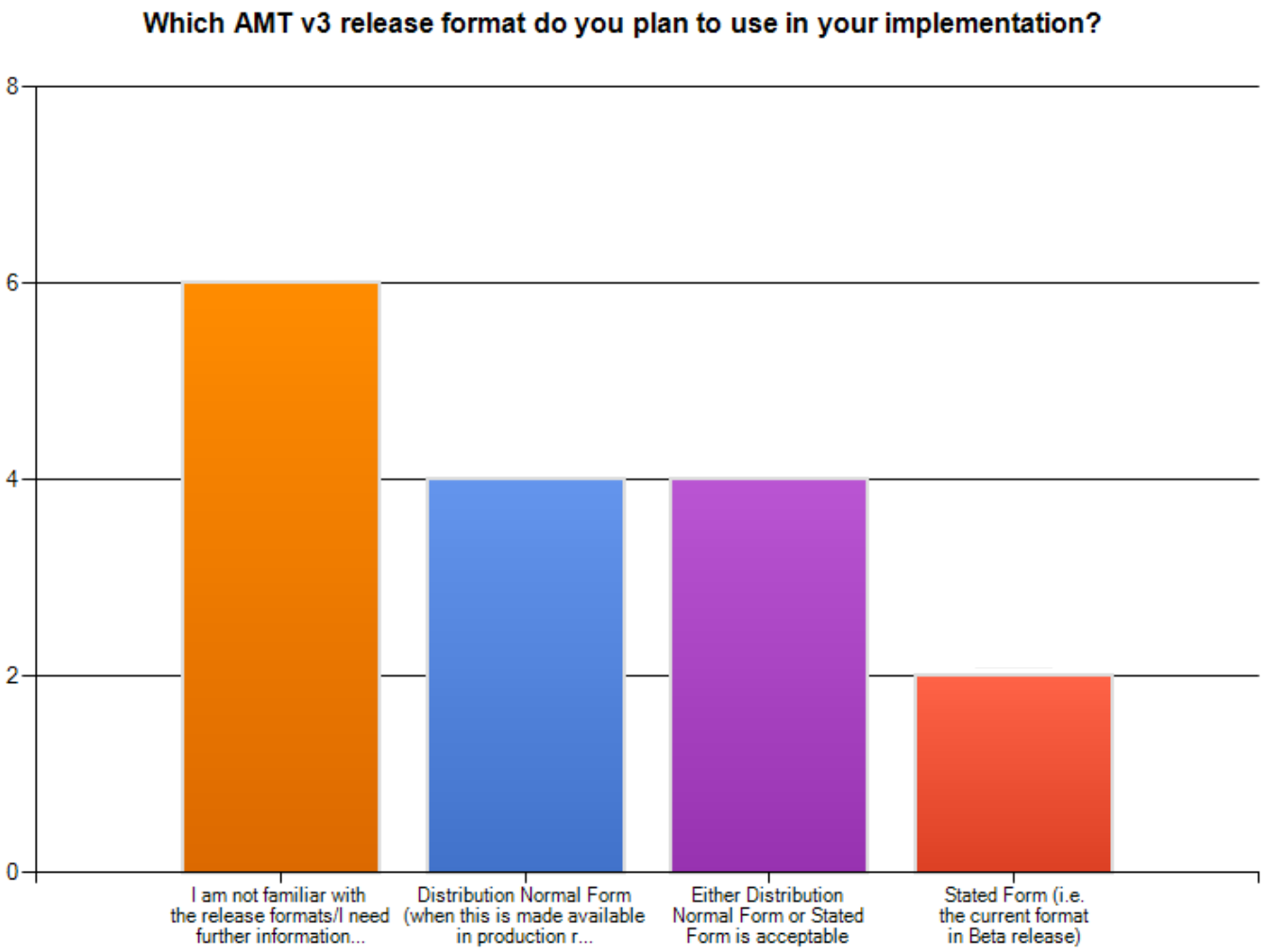
Question 13: Beyond the considerations of the AMT Roadmap, should the existing AMT v3 model be enhanced by modifying existing components or developing new ones?



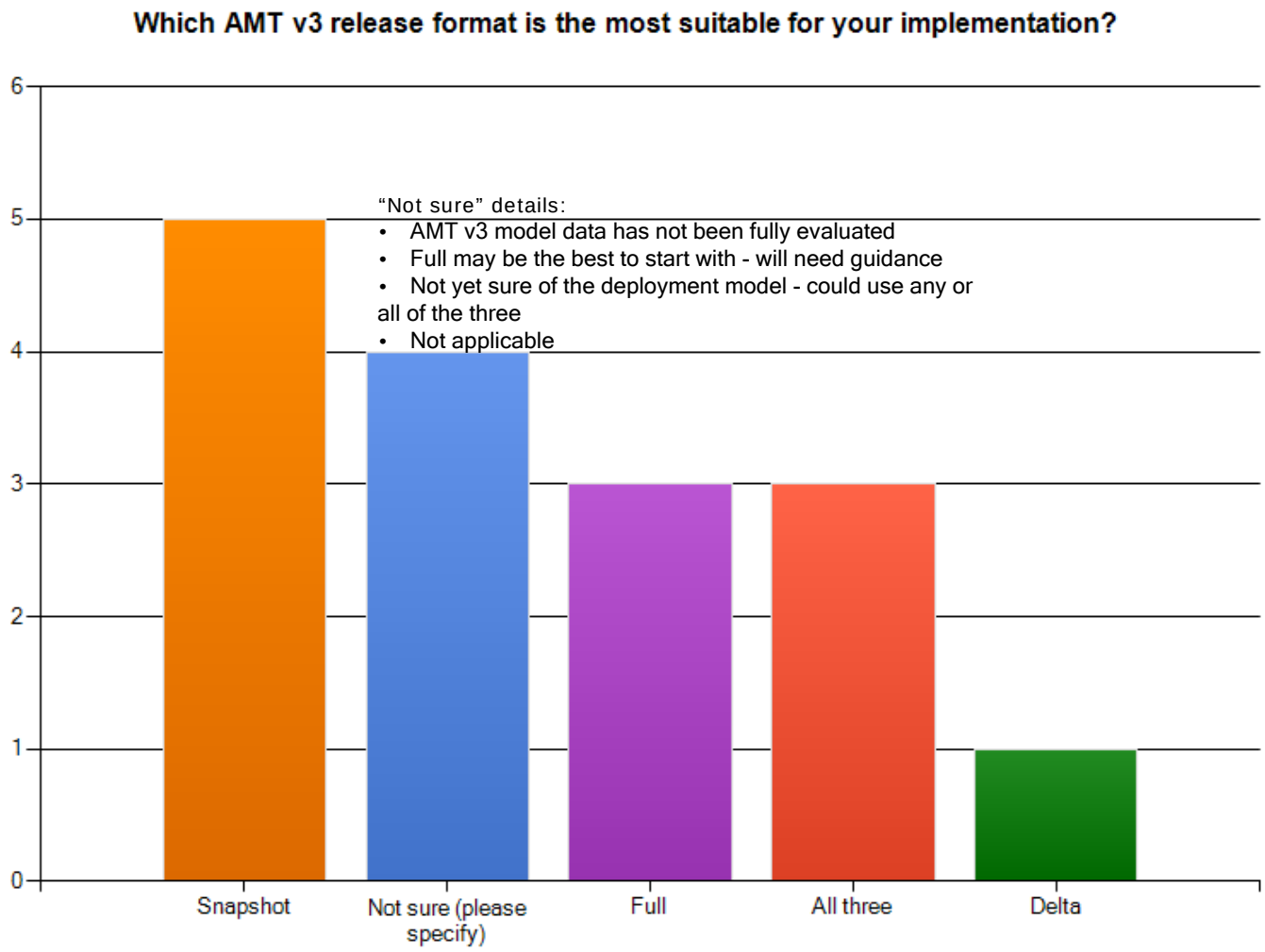
"Not sure" details:
- The AMT v3 model data has not been fully evaluated
- I'm not familiar enough with AMT
- None that I'm aware of at this point in time, though it is still early days for us in terms of implementing AMT
- Depends on the existing user base wants. We are not using AMT codes yet
- Don't know
- Full evaluation not completed
- Get it out the door as soon as possible. not doing so is delaying adoption

"Yes" details:
- Barcodes, please
- We require the Unit of use quantity for the full pack for CTPPs that have multiple MPUUs. For example, Trisequens, 28 tablets, I need the quantity to be 28 and not the quantities for the individual MPUUs
- Should be aligned with SNOMED CT, devices, bandages, etc should *not* be substances, FSNs of ambiguous concepts (e.g. paracetamol + codeine) should be fixed

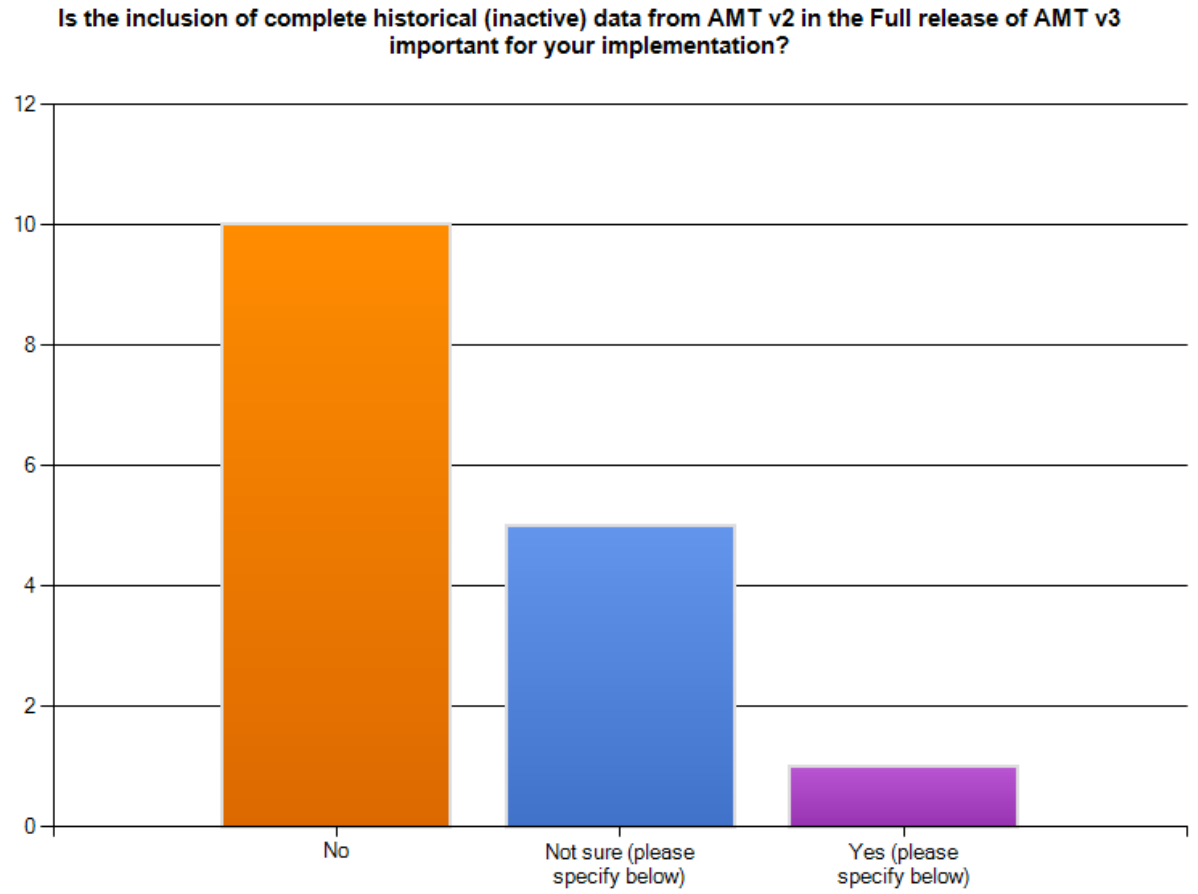
Question 14: Which AMT v3 release format do you plan to use in your implementation?



Question 15: Which AMT v3 release format is the most suitable for your implementation?



Question 16: Is the inclusion of complete historical (inactive) data from AMT v2 in the Full release of AMT v3 important for your implementation?



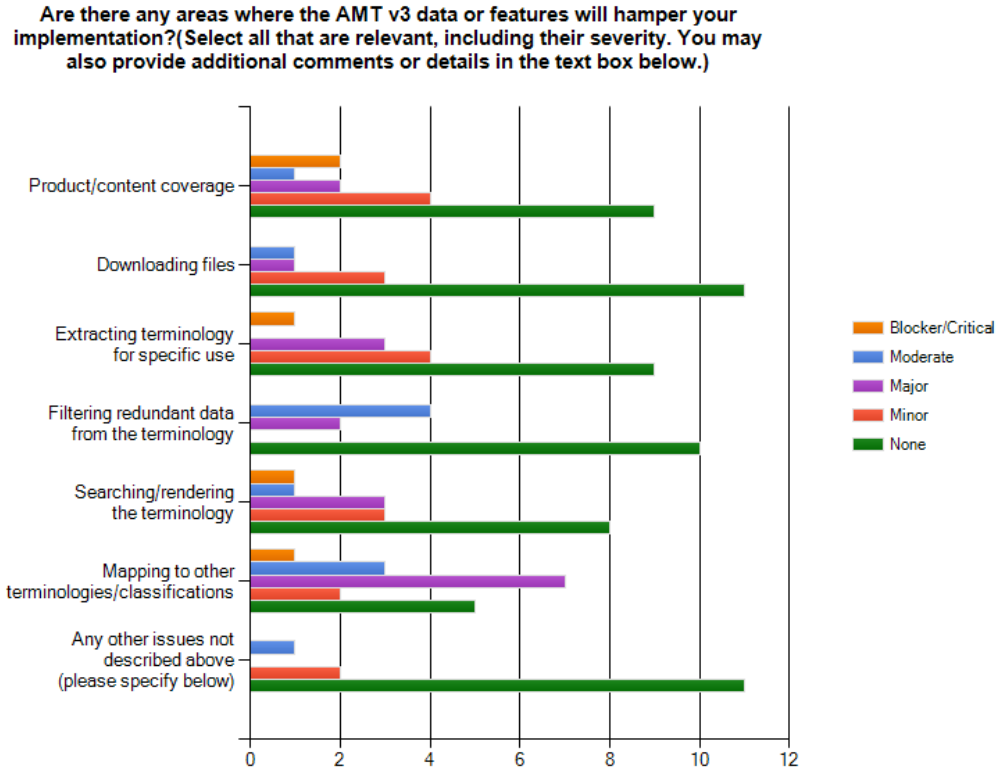
"Not sure" details:

- AMT v3 model data has not been fully evaluated
- It may be in the initial implementation
- Not applicable
- Probably not but I can handle it if present
- Don't know

"Yes" details:

- Any drug database has to capture medications a patient used to take. So any drug that is retired from use because the manufacturer no longer markets it should remain. If there was a mistake in the drugs name however, I am not interested in capturing that information.

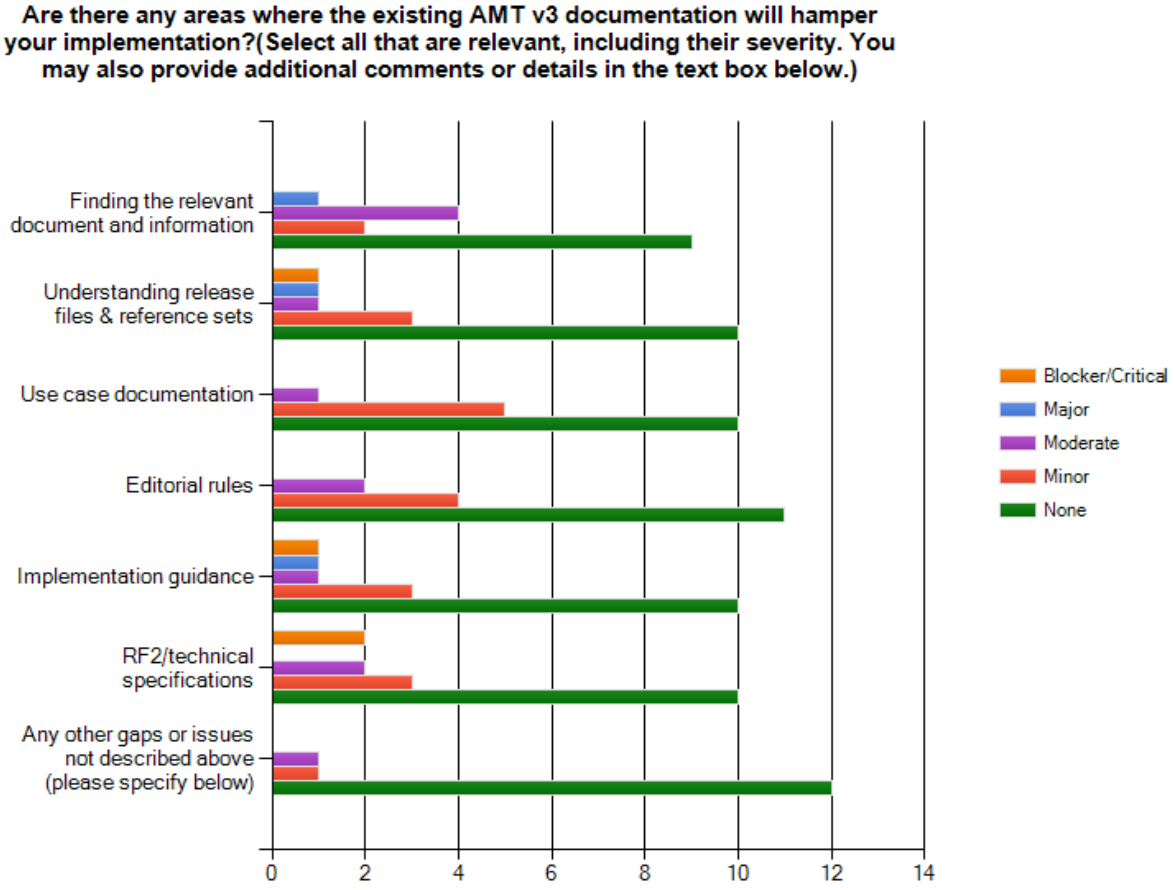
Question 17: Are there any areas where the AMT v3 data or features will hamper your implementation? (Select all that are relevant, including their severity. You may also provide additional comments or details in the text box below.)



Comments:

- The AMT v3 model data has not been fully evaluated
- Needs further investigation
- There could be, we won't know until we try to download and implement
- I tried to enter another comment and was told that it was in an invalid format, maybe too long?
- Have not yet investigated AMT-SNOMED mapping for drugs hierarchies
- Unsure at this stage as we have not implemented
- Refsets linking to PBS Codes, GTINs, and ATCs would be great

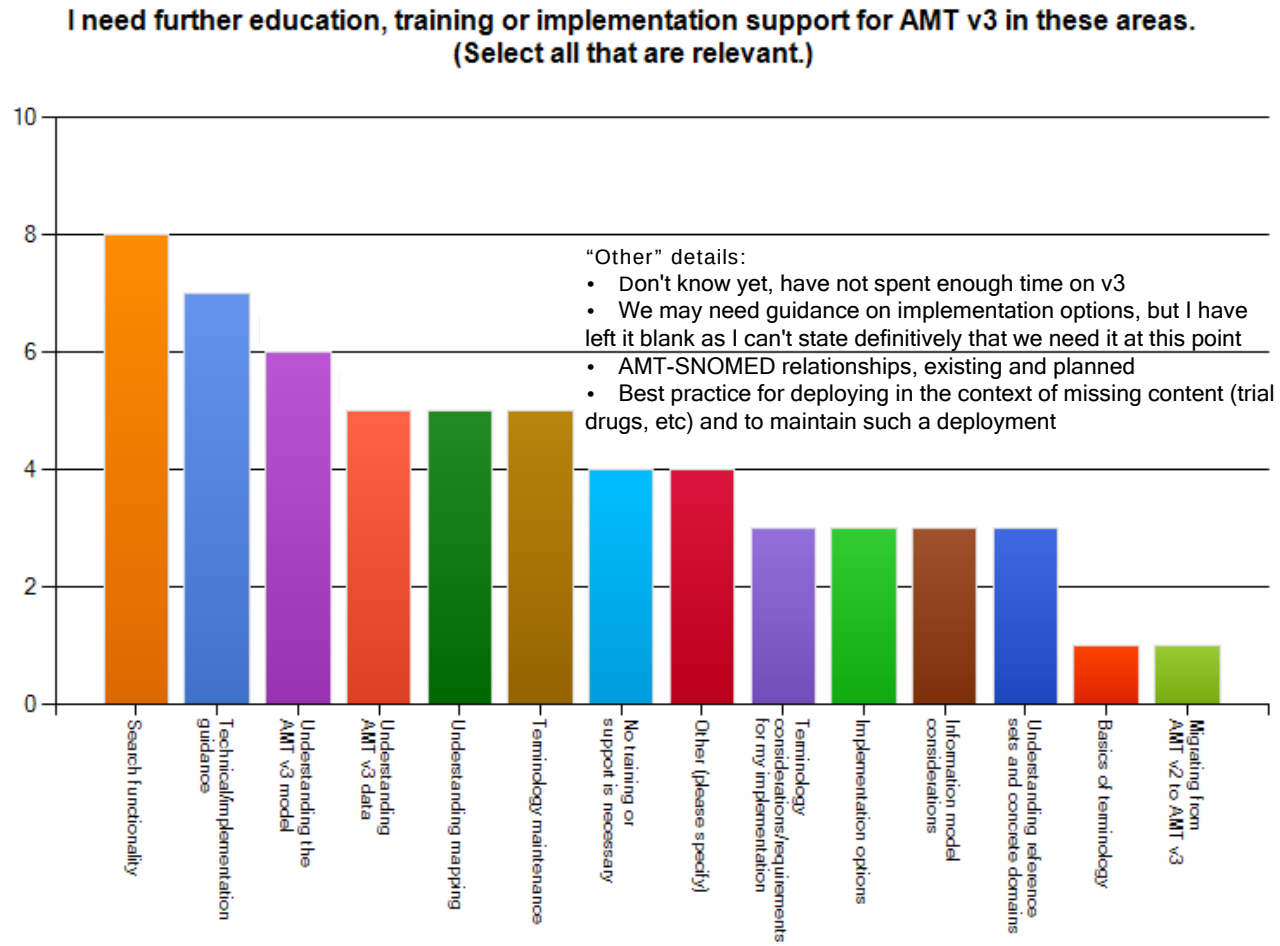
Question 18: Are there any areas where the existing AMT v3 documentation will hamper your implementation? (Select all that are relevant, including their severity. You may also provide additional comments or details in the text box below.)



Comments:

- The AMT v3 model data has not been fully evaluated
- There could be, we wont know until we try to download and implement
- Our requirements are relatively simple so documentation is unlikely to be a problem
- As we have not assessed V3 for implementation we are not sure if it is adequate

Question 19: I need further education, training or implementation support for AMT v3 in these areas. (Select all that are relevant.)

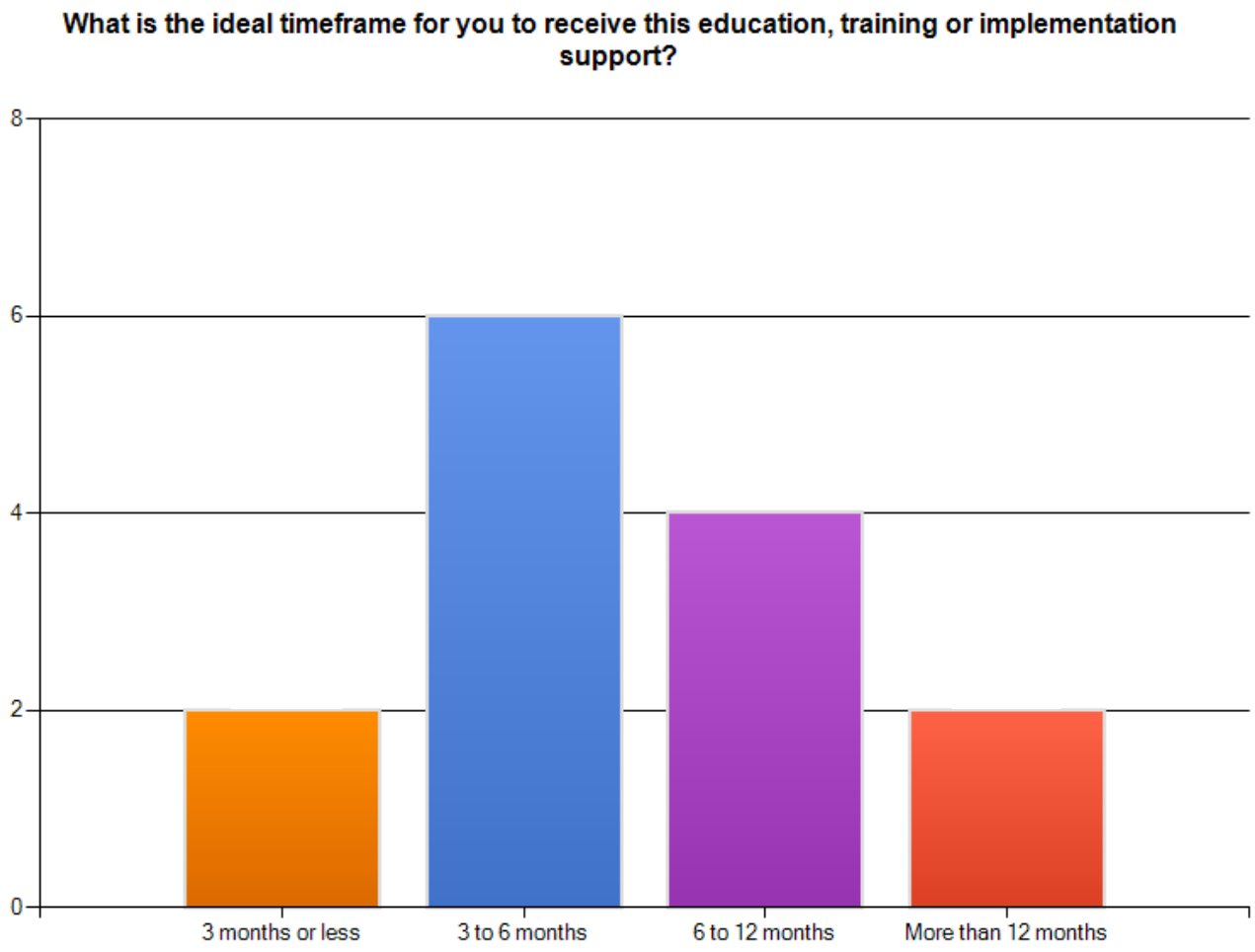


I need further education, training or implementation support for AMT v3 in these areas. (Select all that are relevant.)

Answer Options	Response Percentage	Response Count
Basics of terminology	1.7%	1
Terminology considerations/requirements for my implementation	5.2%	3
Implementation options	5.2%	3
Information model considerations	5.2%	3
Understanding the AMT v3 model	10.3%	6
Understanding AMT v3 data	8.6%	5
Understanding mapping	8.6%	5
Understanding reference sets and concrete domains	5.2%	3

I need further education, training or implementation support for AMT v3 in these areas. (Select all that are relevant.)		
Answer Options	**Response Percentage**	**Response Count**
Terminology maintenance	8.6%	5
Technical/implementation guidance	12.1%	7
Search functionality	13.8%	8
Migrating from AMT v2 to AMT v3	1.7%	1
No training or support is necessary	6.9%	4
Other (please specify)	6.9%	4

Question 20: What is the ideal timeframe for you to receive this education, training or implementation support?



Question 21: Thank you for your input, which will help us to improve AMT v3 for you as well as the wider community of practice. If you have any further comments in relation to AMT v3 or this survey, please provide them in the space below.

The responses below represent feedback not addressed elsewhere in this report. Respondents' comments have been combined and summarised below to preserve the anonymity of responses.

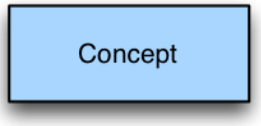
- There are currently no AMT use cases developed for consumers.
- We recommend the development of AMT use cases for consumers, which might include:
  - A consumer creates (and edits) a medicines list based on AMT.
  - A consumer changes the view-states of an AMT-based medicines list.
  - A consumer electronically sends an AMT-based medicines list to a healthcare provider.
  - A healthcare provider electronically sends an AMT-based medicines list to a consumer.
  - A consumer incorporates an AMT-based medicines list into their pre-existing list and reconciles the records.
- The *AMT v3 Technical Implementation Guide* should contain a short overview of description logic.
- Where possible, the explanations in the document should be worded in simple language and be specific to AMT files/data.
- A suite of documents or different sections of a guide that groups all relevant information together for a particular competency could be developed. The competencies might be, for example:
  - Install AMT.
  - Search for a concept.
  - Search for a reference set item.
  - Traverse AMT to define a medicine sufficient for a use case. Repeat for different use cases.
  - Maintain AMT.
- We suggest a few more simple diagrams to help illustrate the programmatic task at hand.
- Provision of support tools to map the ontology to a relational database would be beneficial for developers to abstract the ontology into an easier-to-use paradigm e.g. an API that uses a model that 'talks' to a relational database.
- The need for GTINs is an absolute requirement.

- There needs to be more regulatory requirements to use AMT e.g. the government could start the process of only paying for services related to the SNOMED and AMT codes. This would incentivise vendors to adopt SNOMED CT and AMT. And as a benefit, the interoperability that underpins the basis of NEHTA's mandate would be realised.
- The use of AMT and SNOMED codes across all government departments should also be mandated.
- It is exciting work. The idea of interoperability in health will make things cheaper more efficient and generally better.

Appendix B AMT v3 model diagram conventions

This section describes the non-UML elements used in the AMT v3 model diagram, which are derived from the *SNOMED CT Diagramming Guidelines*[6].

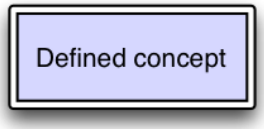
Primitive concept



This diagram element represents a primitive concept.

A primitive concept is a concept that does not have sufficient defining relationships to computably distinguish them from more general concepts (supertypes).

Defined concept



This diagram element represents a defined concept.

A defined concept is a concept that has sufficient defining relationships to computably distinguish it from other concepts.

Reference set

This diagram element represents a reference set member. The target of the dotted line represents the AMT component (e.g. a concept, description or relationship) that is being referenced by this reference set member.

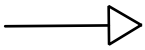
A reference set member is a uniquely identified reference (a row) within a reference set.

A reference set is a set of references to AMT components that may represent additional properties of the components, associations between members of the set with content of another nomenclature, classification or knowledge structure. A reference set may also be a logical subset of AMT components grouped for a particular purpose or those that belong to the same concept class.

Each reference set is distributed as a distinct text file separate to the RF2 core files.

[6] This IHTSDO document is not yet publicly available.

IS A relationship

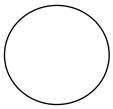


This diagram element represents an “IS A” relationship.

A relationship is an association between a source concept and a destination concept. An “IS A” relationship specifies the super-type (or parent) concept for a given subtype (or child) concept. The child concept shares all the definitional attributes of the parent concept, with optional additional defining characteristics.

The arrow head always points to the parent (super-type) concept.

Attribute group



This diagram element represents an attribute group.

An attribute is a relationship that represents a characteristic of the meaning of a concept or the nature of a refinement. An attribute group is a collection of attributes that are logically put together to allow correct interpretation of the meaning of a concept.

Glossary

Acronym	Term	Meaning
API	**Application Programming Interface**	A set of rules and specifications that enable communication between software programs. Application Programming Interfaces enables interaction between separate software programs, in much the same way that a user interface facilitates interaction between humans and computers.
AMT	**Australian Medicines Terminology**	
ARTG	**Australian Register of Therapeutic Goods**	
BoSS	**Basis of Strength Substance**	The name of the ingredient that the strength of the product is based on. It may be a base, primary modified base or secondary modified base.
BAU	**Business as usual**	
CTPP	**Containered Trade Product Pack**	An AMT product concept.
DNF	**Distribution Normal Form**	
GTIN	**Global Trade Item Number**	
MP	**Medicinal Product**	An AMT product concept.
MPP	**Medicinal Product Pack**	An AMT product concept.
MPUU	**Medicinal Product Unit of Use**	An AMT product concept.
NCTIS	**National Clinical Terminology and Information Service**	
PBS	**Pharmaceutical Benefits Scheme**	
RF2	**Release Format 2**	The new SNOMED CT release format.
SNOMED CT-AU	**SNOMED CT, Australian release**	The Australian extension to the international SNOMED CT terminology.
SQL	**Structured Query Language**	
SNOMED CT	**Systematized Nomenclature of Medicine—Clinical Terms**	
TIG	**Technical Implementation Guide**	
TP	**Trade Product**	An AMT product concept.
TPP	**Trade Product Pack**	An AMT product concept.
TPUU	**Trade Product Unit of Use**	An AMT product concept.
UML	**Unified Modelling Language**	

References

1. NEHTA. *AMT v3 Technical Implementation Guide*. Sydney: NEHTA; 2013. Available from: http://www.nehta.gov.au/implementation-resources/ehealth-foundations.